REMARKS

Twice-a-day composition claims 23-26 were rejected as being indefinite under 35 U.S.C. §112, 2nd ¶; those claims have been cancelled. The Examiner maintained the rejection of tablet composition claims 1-2 and 4-5 as being obvious under 35 U.S.C. § 103(a), over U.S. Patent # 4,758,424; issued July 19, 1988; to Denick *et al.* (hereinafter "Denick") in view of Japanese Patent JP 64007786 issued May 18, 1964; to Aida (hereinafter "Aida"); those claims have been cancelled. The Examiner maintained the rejection of composition and method claims 1-6 as being obvious over International Application WO 96/22762; published August 1, 1996; in the name of Kupper (hereinafter "Kupper") either alone or in view of U.S. Patent #5,663,415; issued September 2, 1997; to Chopdekar *et al.* (hereinafter "Chopdekar"); those claims have been cancelled. The Examiner maintained the rejection of Claims 15-30 (each of which recited active ingredient ranges or amounts) as being obvious over Kupper either alone, or in view of Chopdekar in further view of U.S. Patent #5,164,398; issued November 17, 1992; to Sims *et al.* (hereinafter "Sims"); twice-a-day claims 23-30 have been cancelled.

Amended claims 15-22 are each directed either to a composition or to a method for treating cough with the claimed active ingredient combination of carbetapentane tannate and guaifenesin either in a tablet form or in a suspension form. Each of amended claims 15-22 further recites either a range for each active ingredient or actual amounts for each active ingredient. New dependent method claims 31-34 add a twice-a-day element to each of the tablet-reciting or suspension-reciting, range-reciting or amount-reciting, method claims. Claims 15-22 and 31-34 as thus recited are definite under 35 U.S.C. §112 2nd ¶, and nonobvious under 35 U.S.C. §103(a) in view of the art of record.

I. The Indefiniteness Rejection of Cancelled Claims 23-26 (Twice Daily Composition Claims) Was Unfounded; The Pending Claims Are Not Indefinite

In the *third* Office Action dated January 15, 2004, the Examiner added four *new* references to the instant prosecution. Two of those references had been cited in Applicants' IDS filed three months *prior* to the mailing date of the *second* Office Action, but those references were oddly enough not subsequently applied in that *second* Office Action, notwithstanding the Examiner's acknowledged receipt and consideration of that IDS *in* that second Office Action. Initially applying the four new references in the *third* Office Action, the Examiner refused to give "patentable weight" to the preamble recitation of "twice-a-day" in the BID-dosed composition claims 23-26. Those claims had been presented in response to the second Office Action to clearly distinguish over the teachings of Sims—the *only* reference asserted in either the first or second Office Actions.[1] In support of her third Office Action's refusal to ascribe "patentable weight" to the *twice-a-day* aspects of composition claims 23-26 the Examiner argued that such preamble recitation was "intended use." Applicants amended the claims in response thereto, but were somewhat perplexed by the argument, since a search of the USPTO data-base revealed that this Examiner (from her first allowed patent to her most recently allowed patent) has *consistently* allowed pharmaceutical composition claims wherein "intended use" was an *express* preamble recitation:

> "1. A carrier composition **for use as** a vehicle in the manufacture of soft or hard

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[1] In pertinent part, MPEP §707.02 provides that:

> "The supervisory patent examiners should impress their assistants with the fact that **the shortest path to the final disposition of an application is by finding the best references on the first search and carefully applying them**.
>
> **The supervisory patent examiners are expected to personally check on the pendency of every application which is up for the third or subsequent *>Office< action with a view to finally concluding its prosecution**." (emphasis added).

gelatin capsules comprising"—U.S. 6,365,181.

"1. A powder **for use in** a dry powder inhaler, the powder consisting of"—U.S. 6,528,096.

"1. A solution composition **useful in** the process of tattoo removal, consisting of:"—U.S. 6,773,698.

Applicants' *Attorney* was the more perplexed by the argument upon considering the still many *more* pharmaceutical composition claims that he has prosecuted before the same Examiner, wherein very similar "*once-a-day*" language was a preamble recitation:

U.S. 6,730,320
U.S. 6,723,341
U.S. 6,669,948
U.S. 6,667,057
U.S. 6,667,042
U.S. 6,663,891
U.S. 6,663,890
U.S. 6,544,555

The seeming inconsistency of the Examiner's argument notwithstanding, Applicants *then* reluctantly deleted "twice-a-day" from the preambles and amended the bodies of claims 23-26, to define the BID-dosing in terms of "said pharmaceutically effective amount being one half the daily dosage." In the instant (fourth) Office Action (in view of the claims clearly further defining over Sims) the Examiner *now* argues that this amendatory language renders those claims *indefinite*. The Examiner queries *what* the limitation is intended to convey, and further queries *how* half of a daily dosage can be an effective amount.

In the instant Amendment Applicants have cancelled the twice-a-day composition claims and have added new dependent method claims reciting twice–a-day administration. Applicants submit that what is *very* clearly conveyed by the new claims, is that Sims does not teach (either alone or in combination) the twice-a-day aspects of the invention.

Moreover, new method claims 31-34 are not *indefinite*. Whether a claim is definite under

§112, 2nd ¶ presents two separate inquiries. The first is subjective and the second is objective. MPEP §2171. The subjective inquiry is whether the claims set forth the subject matter *that the Applicants regard as their invention.* Applicants regard claims 31-34 as the embodiments of their method invention that provide BID-dosing of the active ingredient combination. The objective requirement of the inquiry is whether the claims *particularly point out and distinctly define the metes and bounds* of the subject matter that will be protected by the patent grant. This objective inquiry distills to whether the scope of the claim is clear to a person of *ordinary skill in the art.* MPEP §2171. That inquiry takes into consideration the *disclosure*, the *prior art*, and the *claim interpretation* that would be given by the *artisan of ordinary skill.* MPEP §2173.02.

Though Applicants have deleted the phrase "a pharmaceutically effective amount" from *all* of their claims, this has been done *only* to placate the Examiner. Applicants stress that this Amendment has not been effected for *any* reason that would relate to patentability. To be sure, MPEP §2173.05(c) III states that the "common phrase" *an effective amount* is not *per se* indefinite. Indeed, each of the Dennick, Sims, and Kupper *prior art* references that the Examiner has relied upon in this prosecution uses virtually identical claim language:

> "16. A medicated chewing gum product **containing a therapeutically effective amount** of medicament drug which comprises:..." Denick (emphasis added).
>
> "1. A pharmaceutical composition for use in the treatment of pain and inflammation and the relief of cough and cold symptoms in a mammalian organism and adapted for unit dosage oral administration said composition comprising:
> (i) **an analgesically and anti-inflammatory effective amount** of (S)-ibuprofen, or a salt thereof, substantially free of (R)-ibuprofen; and
> (ii) **an antitussively effective amount** of at least one antitussive selected from codeine, hydrocodone, dextromethorphan or a therapeutically active stereoisomer thereof substantially free of its other stereoisomers." Sims (emphasis added).
>
> "1. A pharmaceutical composition suitable for oral administration **comprising a safe and effective amount** of at least one unpleasant tasting, pharmaceutical active, characterized in that it further **comprises an effective amount**, preferably from 0.01% to 2%, of an aloe vera component,..." Kupper (emphasis added).

Furthermore, the Federal Circuit's predecessor court in In re Watson long ago informed that the claim term "an effective amount" is **not** indefinite if the claim states the "function" that is to be achieved therewith:

> "The issue here is whether the phrase "an effective amount" used in independent claim 1 is indefinite under 35 U.S.C. s 112, second paragraph. [FN4] Dependent claim 3 was not rejected on this ground.
>
> The examiner and the board expressed the view that claim 1 does not recite the effect sought to be produced or the purpose for which the amount is effective, and the examiner cited In re Frederiksen, *477 supra, as authority for this ground of rejection.
>
> **Frederiksen is authority for the proposition that the phrase "an effective amount" is indefinite when the claim fails to state the function which is to be achieved.** The appealed claim in Frederiksen recited "an effective amount of the diethylamino ethanol ester of phenaceturic acid." The claim completely failed to state the effect sought to be produced.
>
> **The present case is distinguishable, however, since claim 1 recites "an effective amount of a germicide suitable for use in oral hygiene." The very term "germicide," used in this claim, indicates that germicidal action is the effect sought to be produced. Hence, the recitation points out both the effect sought to be produced and the purpose of that effect, viz, germicidal action in oral hygiene.**
>
> **Moreover, the claim language must be read in light of the application disclosure as it would be interpreted by one of ordinary skill in the art.** See In re Moore, 439 F.2d 1232, 58 CCPA 1042 (1971). **Those skilled in the art will be able to determine from the disclosure, including the examples, what an effective amount of germicide is.** Cf. In re Mattison, 509 F.2d 563 (CCPA 1975). In the context of the claimed subject matter, the disputed phrase reasonably defines the metes and bounds of the invention to one of ordinary skill in the art. See In re Halleck, 422 F.2d 911, 57 CCPA 954 (1970); and In re Fuetterer, 319 F.2d 259, 50 CCPA 1453 (1963); cf. In re Caldwell, 319 F.2d 254, 50 CCPA 1464 (1963). We hold that claims 1, 2 and 4-6 are not indefinite under s 112, second paragraph.
>
> The decision of the board is reversed." In re Watson, 571 F.2d 465, 476-77 (C.C.P.A. 1975)(emphasis added).

Like the claims in Watson, each of the cancelled, amended, and new claims actually recites the intended function, to wit:

> "...**for the symptomatic relief of cough** associated with respiratory tract conditions resulting from the common cold, bronchial asthma, and acute and chronic bronchitis..." (Common to *all* pending and prior claims)(emphasis added).

Moreover, with specific reference to the *definiteness* of the claim term "an effective amount" MPEP §2173.05(c) III states that "[t]he proper test is whether or not one skilled in the art could determine **specific values** for the amount based on the disclosure." (emphasis added). This MPEP section militates even more favorably for the *definiteness* of each of the cancelled, amended, and new claims, since, *unlike* the claims in Watson (which *were* found to be definite), each of the cancelled, amended, and new claims recites or incorporates the **specific values** (ranges or amounts) that are *pharmaceutically effective*, thereby leaving *nothing* for the artisan to have to speculate about:

> Claims 15 & 19 "...said active ingredients consisting of carbetapentane tannate in an amount of from **about 50 mg. to about 75 mg., per tablet**, and guaifenesin in an amount of from **about 100 mg. to about 300 mg., per tablet**." (emphasis added).
>
> Claims 16 & 20 "...wherein said tablet contains **about 60 mg.** of carbetapentane tannate, per tablet, and **about 200 mg.** of guaifenesin, per tablet." (emphasis added).
>
> Claims 17 & 21 "...said active ingredients consisting of carbetapentane tannate in an amount of from **about 20 mg. to about 40 mg., per 5 ml. of suspension**, and guaifenesin in an amount of from **about 50 mg. to about 150 mg., per 5 ml. of suspension**." (emphasis added).
>
> Claims 18 & 22 "...wherein said suspension contains **about 30 mg.** of carbetapentane tannate, per 5 ml. of suspension, and **about 100 mg.** of guaifenesin, per 5 ml. of suspension." (emphasis added).

Additionally, the artisan of ordinary skill when reading the other objected-to portion of the cancelled claim language—"being one half the daily dosage"—in light of the application disclosure (as Watson requires it to be read), could not fail to appreciate that those cancelled claims were directed to a *twice-a-day* cough / cold composition having definite amounts of active ingredients per BID-dosed tablet or BID-dosed suspension:

> **"The compositions described herein are designed to be taken twice a day with the immediate expectorant action of guaifenesin and the prolonged**

> **antitussive action of carbetapentane tannate**. The compositions of the present invention may be prepared for oral administration in the form of powders, capsules, elixirs, syrups and the preferred forms of tablets and suspensions.
>
> Tablets containing the unique carbetapentane tannate and guaifenesin compositions of the present invention are prepared in a conventional manner by the addition of suitable pharmaceutical carriers including fillers, diluents, colorants, lubricants and the like as well as conventional and well known binding and disintegrating agents. **Each tablet would contain approximately 50 to 75 mg of carbetapentane tannate and 100 to 300 mg of guaifenesin.** A typical tablet composition of the present invention containing starch, dibasic calcium phosphate, colorants, magnesium stearate, methylcellulose, polygalacturonic acid, povidone and talc, as described in **Example 1 which follows, is prepared by well known conventional tabletting techniques** such as those disclosed in U.S. Patents Nos. 3,018,221; 2,798,024 and 2,757,124." (Specification pages 3-4)(emphasis added).
>
> "**Suspensions of the compositions of the present invention are prepared in a conventional manner such that each 5 mL (one teaspoon) contains 20 to 40 mg carbetapentane tannate and 50 to 150 mg guaifenesin**. Additionally, the suspension formulations may contain colorants, natural and artificial flavors, glycerin, kaolin, magnesium aluminum silicate, methylparaben, benzoic acid, sorbic acid, pectin, purified water, saccharin, sodium hydroxide and sucrose or sorbitol. **Example 2, which follows, is illustrative of a typical suspension formulation of the present invention prepared by conventional well known compounding techniques**." (Specification pages 4-5)(emphasis added).

Accordingly, although the instant Amendment has deleted the phraseologies "a pharmaceutically effective amount" and "being one half the daily dosage" these deletions are not related to patentability, since one of ordinary skill in the art referencing the disclosure, including *Examples I* and *II*, would have no doubt that the "pharmaceutically effective amounts" of carbetapentane tannate and guaifenesin providing "one half the daily dosage" are those falling within the *claimed* ranges and the *claimed* amounts that were, and are, *recited* in those cancelled, and now-amended, claims. The conclusion that the instant Amendment was not necessitated by concerns of patentability is further supported by the fact that the deleted language was similar to that used to delimit the subject matter claimed in the Examiner-cited prior art references. New claims 31-34 reasonably define the metes and bounds of the twice-a-day method embodiments of the

invention to one of ordinary skill in the art, and therefore they are not indefinite under §112, second paragraph.

II. The Pending Claims Are Not Obvious Over Denick In View of Aida

The Examiner cites Denicks's Example 5 for the teaching of a chewable cough tablet containing 100 mg. of guaifenesin. The Examiner concedes that "Denick *et al.* do not teach the incorporation of carbetapentane tannate." The Examiner then cites Aida for teaching "the use of carbetapentane tannate as a non-irritant cough suppressor." The Examiner argues that the claimed combination of active ingredients would be obvious, and that "the motivation to combine the references is that one would expect an additive effect by combining two known cough agents, absent unexpected resulting [sic results] proving a synergistic effect." The Examiner asserts that one would be motivated to add a second cough agent to provide an additive effect since both drugs are taught to be cough agents and are utilized in the art for the same purpose." The Examiner further asserts that "Denick teaches the known use of guaifenesin for suppressing cough in a taste masked product."

The Examiner's theory is incorrect in both fact and law. First, Applicants would note that while the claimed antitussive, carbetapentane tannate, is a cough suppressor, as correctly noted by the Examiner's citation to Aida, the Examiner's reference to Denick is completely wrong. Denick does not teach "the known use of guaifenesin for suppressing cough" as the Examiner asserts. In fact, Denick does not attribute cough-suppressing abilities to any drug, or to any class thereof. Indeed, Denick's only use of the word "suppressant" is with regard to the "[A]ppetite supressants such as phenylpropanolamine hydrochloride, and caffeine[.]" (Col. 4, line 19).

As Denick *correctly* notes, guaifenesin is an *expectorant*. (Col. 4, line 22). Expectorants

are not cough *suppressors*; they are cough *promoters* that increase bronchial mucous secretion, resulting in increased liquefaction of the sputum. (See Page 613, *Over-the Counter Treatment of Cough and Colds*, by Mason; The Pharmaceutical Journal, Vol 269; October 26, 2002; attached hereto as Exhibit E). Clearly, the Examiner's argument that the claimed components have the same purpose could not be more inaccurate. As a necessary corollary the Examiner's assertion that the artisan would be motivated to make the Examiner's asserted combination in view of expectations of an "additive effect" of two cough agents is also inaccurate. That conclusion is supported by suggestions in the art that directly conflict with the Examiner's argument:

> "**In addition, some cough medicines contain other ingredients that may cancel out Guaifenesin's effects.** Coughs Suppressants such as Codeine, for example, work against Guaifenesin because they discourage coughing up the secretions that the expectorant loosens." (See Page 1, *Pharmaceutical and Drug Manufacturers* attached hereto as Exhibit F)(emphasis added).

> "7. Most over-the-counter cold remedies contain some combination of acetaminophen and various decongestants, antihistamines and cough suppressants. **Some experts believe that these ingredients may actually work against each other. For example acetaminophen may increase nasal congestion while the decongestant decreases it.** If a cold is making you extremely uncomfortable, and you feel you must take something for it, it is better to take a single ingredient product appropriate for the particular symptom you are treating." (See Page 2, *It's Cold Season Again!*, by Arya; Trinity Health; attached hereto as Exhibit G). (emphasis added).

Accordingly, one of ordinary skill in the art would not expect the claimed combination of ingredients to have an "additive effect."

And, even if the artisan would expect the claimed active combination to be additive in effect, which he would not, the Board of Patent Appeals and Interferences has stated unequivocally that an artisan's expectation of an "additive effect" does not establish a *prima facie* case of obviousness:

> "The Examiner states that "it would have been obvious for one skilled in the art to add the doubling circuit of Tatsumi between the oscillator signal (within OSC) and the charge pump of Ito to obtain the expected result of providing a

> regulated signal with a variable duty cycle thereto." (See answer at page 4.) **The Examiner further embellishes the above motivation statement by stating that the modification would provide "a combination having the expected additive result of a highly regulated clock signal with variable duty cycle being provided to the charge pump.** Such advantage will provide greater control and stability of the level of the voltage provided at Vout" (See answer at page 5.) (Emphasis added.) Appellants argue that the Examiner has not provided a """teaching or even a suggestion in either the Ito patent or the Tatsumi patent to combine them into applicants' advantageous combination." (See brief at page 9.) Appellants further argue the lack of an adequate motivation to combine the references. Appellants argue that no reasonable suggestion exists in the prior art to point the way to the modification as set forth by the Examiner. (See brief at page 8.) We agree with appellants that the prior art references do not disclose or suggest an adequate motivation to combine the teachings.
>
> Appellants argue that "their claimed arrangement does not just 'merely' increase the frequency, but it takes advantage of the insight that the one capacitor of the single charge pumping circuit can be operated more effectively in response to the selected signal without increasing the capacitance of and therefor the size of the capacitor." (See brief at pages 5-6.) Clearly, the individual prior art references applied by the Examiner have not recognized this advantage nor has the Examiner set forth a line of reasoning for the combination to have recognized an advantage. **The mere fact that the skilled artisan would achieve the "additive result" does not make it prima facie obvious to combine the teachings as the Examiner asserts. Some motivation to achieve this additive result must be in the prior art or from the common sense or from known engineering knowledge.**
>
> The prior art references are silent with respect to the details of the oscillator or the speed of operation. **Moreover, the Examiner has not set forth any additional rationale beyond the mere conclusion that the combination would have been obvious and that the additive result would have been achieved.** The Examiner did not set forth any additional line of reasoning such as the relationship between frequency and size of capacitance, the desire to read/write at a faster rate to increase clock speed or the cost of increasing the speed of the clock as a consideration by the skilled artisan. **Therefore, the Examiner has not set forth a prima facie case of obviousness. Therefore, we will not sustain the rejection of claims 1-5.**" Ex Parte Koelling, 1997 WL 1947961, *3 (Bd. Pat. App. & Interf.)(emphasis added).

In the instant case there is no motivation in either Aida or Denick to combine the claimed actives (Aida teaches no active cough component other than carbetapentane tannate and Denick does not teach carbetapentane tannate). Moreover, the "common sense" in the cough syrup art (as quoted above from Exhibits F & G) suggests that not only are cough combination products **not** additive in their effect, but that in some instances they might be counter-productive and self-defeating,

particularly where guaifenesin is a component.

Applicants have earlier argued that the Examiner's piecemeal application of isolated teachings in the art demonstrates a failure to consider the teachings of each prior art reference *as a whole*, as they are required to be applied. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983). Specifically, applicants have argued that Denick *as a whole* is directed to masking harsh-tasting actives and that Aida *specifically* teaches that carbetapentane is *not* harsh-tasting. And, when thus *holistically* (and therefore properly) appreciated by the artisan, the teachings of the art would necessarily militate against the combination urged by the Examiner. In response the Examiner has raised In re Heck (without reference to court, volume, page, or any other identifying citation) for the ostensible proposition that the *selective* parsing of a reference's isolated teachings is not infirm, because those isolated teachings "are part of the literature of all they contain[.]" This language actually originates from In re Lemelson, 397 F.2d 1006, 1009 (C.C.P.A. 1968) which when read *as a whole* itself contradicts the Examiner's position:

> "As we said in In re Boe, 355 F.2d 961, 53 CCPA 1079 (1966), '**All of the disclosures in a reference must be evaluated for what they fairly teach one of ordinary skill in the art**.' The use of patents is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for **all they contain**." (emphasis added).

When the artisan considers "*all* of the disclosures" of the references "for *all* they contain" those disclosures would "fairly teach" that Denick is directed to the masking of harsh tasting actives and that Aida expressly teaches that carbetapentane has no such harsh taste. Lemelson's assurance that a patent's use as a reference might not be "limited" by the intent, focus, or problem of the patentee, does not absolve the Examiner of her obligation to consider the teachings of the references in their entireties, as W.L. Gore *supra* and other post-Lemelson

decisions affirm:

> "Pengilly and Munro individually teach methods for the production of PET which differ, in different respects, from that claimed by Rhinehart. **A determination under 35 U.S.C. s 103, however, requires consideration of the entirety of the disclosure made by the two references to those skilled in the art.**" In re Rinehart, 531 F.2d 1048, 1051 (C.C.P.A. 1976).

In its *entirety* Denick is concerned with the problem of masking the flavor of harsh-tasting actives. In its entirety Aida teaches that carbetapentane tannate is not harsh tasting and therefore does not present the formulator with such a problem. If anything, the references teach away from the claims. Accordingly, the claimed combination of actives would not have been obvious over Denick in view of Aida.

II. The Pending Claims Are Not Obvious Over Kupper By Itself, Nor In View Of Chopdekar

The Examiner cites *Example II* of Kupper as teaching a syrup containing dextromethorphan HBr and guaifenesin, and page 4 of Kupper for its inclusion of the carbetapentane free base among a lengthy list of known antitussive free bases. Significantly, Kupper does *not* mention tannates among an even lengthier list of "pharmaceutically acceptable salts." (page 4). The Examiner then cites Chopdekar, which teaches the preparation of *antihistamine* tannates, but which erroneously lists carbetapentane among its Markush group of 15 known *antihistamines*. Notwithstanding that each of the Examiner's four *other* references of record *correctly* identifies carbetapentane as an *antitussive*, and not as an *antihistamine*, she ignores this clear and erroneous departure from the *knowledge of one of ordinary skill in the art* and applies the mistaken Chopdekar reference anyway. To make matters worse the Examiner then takes complete license with this irrelevant reference by wholly mischaracterizing an isolated teaching.

The Examiner asserts that the artisan would be motivated to substitute carbetapentane

tannate for the dextromethorphan HBr of Kupper because Chopdekar teaches that the tannate salt "form is stable and may be administered in its [sic that] form without any side effects." The Examiner further argues that the substitution would "yield a stable composition with **less** side effects when the composition is administered." And further argues that "Chopdekar teaches the tannate salt is more stable and **reduces** side effect[s]." The isolated teaching of Chopdekar that the Examiner cites for this substitution motivation actually reads as follows:

> "Antihistamine compounds in the form of their free bases as well as their salts, e.g. hydrochloride, maleate, tannate, etc. are well known. Frequently, it is desirable to utilize the antihistamine in the form of its tannate salt, because such salt is generally quite stable and may be administered **in such form without any untoward side effects**." (col. 1, lines 13-18)(emphasis added).

In other words, the use of tannate salts when administering *antihistamine* compounds may be preferable, because tannate salts **do not exacerbate** or **add** untoward side effects to those that the *antihistamine* compound may *already* be bringing to the formulation! The Examiner attempts to twist this antihistamine teaching into a motivating suggestion that tannate salts, as opposed to other salt forms, have some side effect diminishing quality that would commend their use with side effect-prone *antihistamine* free bases. That is clearly not the teaching of Chopdekar, neither *as a whole* nor as the Examiner's distorted part. And even if that were Chopdekar's teaching, which it is not, carbetapentane is an *antitussive*, not an *antihistamine*, and the artisan of ordinary skill knowing same to be true would not apply *any* of the teachings of Chopdekar in formulating the instantly claimed *antitussive*-containing invention.

The Examiner also argues that it would be obvious to substitute the dextromethorphan of Kupper's *Example II* with carbetapentane because each is an antitussive and therefore functionally equivalent. The Examiner further argues, without case citation, that it is *prima facie* obvious to substitute functional equivalents.

The Examiner's theories are incorrect in both fact and law. First, the prior art recognizes

that not all *coughs* are equivalent—they are either wet (productive) or dry (non-productive).

> "Coughs vary from mild to severe, and come in two general forms: productive and nonproductive. **Productive coughs are those that produce fluid or mucus**, and are often caused by lung infections. **Nonproductive coughs do not bring to the surface fluid or mucus**." (See page 1 of *Cough Description*, by QuestHealthLibrary.com, copyright 2000; attached hereto as Exhibit H).

The prior art *further* recognizes that not all *cough suppressants* are functionally equivalent *vis-a-vis* these two different types of coughs, and that dextromehtorphan is recommended for dry / non-productive cough.

> "**Dextromethorphan is a cough suppressant for short-term treatment of nonproductive coughs**." (See Dextromethorphan, by Healthwell, Last Update: 02-Aug-99; attached hereto as Exhibit I).

The instant claims are directed to compositions and methods for treating cough resulting from the *common cold, bronchial asthma, and acute and chronic bronchitis*. It is recognized in the prior art that dextromethorphan should not be used to treat cough associated with asthma, as claimed, or to treat wet / productive (phlegm-producing) coughs in general:

> "**Do not use dextromethorphan for treatment of a chronic cough that is due to smoking, asthma, emphysema, or problems that cause a large amount of phlegm**." (See page 1 of *E*Drug Digest, Last updated 5/2/00; attached hereto as Exhibit J).

In fact, §341.74(b)(3)(vii)(c)(2) of Title 21 of the Code of Federal Regulations, which regulates Food and Drug Administration, actually *requires* that products containing dextromethorphan be labeled in accordance with the above-noted prior art-recognized shortcomings:

> "Do not take this product for persistent or chronic cough such as occurs with smoking, **asthma**, or emphysema, **or if cough is accompanied by excessive phlegm (mucus)** unless directed by a doctor." (See 21 C.F.R. §341.74(b)(3)(vii)(c)(2); attached hereto as Exhibit K)(emphasis added).

It is further recognized in the prior art that wet, mucous-producing coughs are symptomatic of both *acute* and *chronic* bronchitis, as further claimed:

> "Signs and Symptoms

> Acute bronchitis:
>
> • **Cough that produces mucus or pus...**
>
> Chronic bronchitis:
>
> • **Cough that produces excessive amounts of mucus or pus...**" (See page 1 of Bronchitis, by University of Maryland Medicine, review date August 1999; attached hereto as Exhibit L)(emphasis added).

It is further well-known that the common cold, as still further claimed, similarly manifests itself in the form of wet / productive / mucous-producing cough:

> "**It is normal to have a productive cough when you have a common cold**." (See page 1 of *Coughs*, by Youngerman-Cole, Yale New Haven Health; attached hereto as Exhibit M).
>
> "**Also, the flu usually produces a dry cough, rather than the loose or wet cough associated with a cold.**" (See page 4 of Health Connections, *Make this your year to beat the flu*, by Saberman, MD; attached hereto as Exhibit N)(emphasis added).

Accordingly, since both the prior art and FDA's promulgations recognize that dextromethorphan should not be used to treat cough associated with *asthma*, or to treat cough associated with the productive / wet / mucous-producing coughs as are known to accompany *acute* and *chronic bronchitis*, and the *common cold*, the artisan would not consider dextromethorphan HBr to be the functional equivalent of the instantly-claimed carbetapentane tannate. Carbetapenentane tannate is instantly claimed with guaifenesin to treat these types of cough, and dextromethorphan is *contraindicated* for treatment of these types of cough.

Second, Applicant's are not claiming carbetapentane, or an antitussive salt; they are claiming *carbetapentane tannate* in combination with *guaifenesin*. Kupper's *Example II* doesn't teach dextromethorphan free base, or a general desirability of mixing an antitussive with an expectorant; it teaches *dextromethorphan HBr* with *guaifenesin*—though, *as a whole*, Kupper teaches *how to mask the bitterness of harsh tasting actives*. Even if the test for obviousness was one that considered the *functional equivalence* of components, which it is not, carbetapentane

tannate is not the functional equivalent of dextromethorphan HBr. Applicants have already argued at length, and submitted rebuttal art establishing, that hydrobromides are fast releasing and that tannates are slow releasing. The Examiner does not challenge this functional dissimilarity.

The Merck Index indicates that both carbetapentane and dextromethorphan are in the therapeutic category of *antitussives*. (See Pages 292 and 1392 of The Merck Index, Twelfth Edition 1996, attached hereto as Exhibit O). However, both the Merck Index and the art in general, recognize that dextromethorphan is an *opioid*:

> "**Note: Racemethorphan and levomethorphan are controlled substances (opiates)** listed in the the U.S. Code of Federal Regulations, Title 21 part 1308.12 (1995)." (Exhibit O)(emphasis added).

> "**Dextromethorphan is an opioid**, which puts it in the same class of drugs as heroin and PCP, better known drugs of abuse." (See Page 1 of *Cough Syrup Abuse*, by Cox, MD, FAAP; The Informed Parent 8/30/04; attached hereto as Exhibit P)(emphasis added).

Whereas the art distinguishes carbetapentane as being a *non-opioid* cough suppressant / antitussive:

> "**Carbetapentane is a nonopioid cough suppressant**" (See page 2 of U.S. Brand Names Tussi-12 ® D; Tussi-12 ® DS; attached hereto as Exhibit Q)(emphasis added).

It is well-known in the art that *all* opioids have some commonality of untoward side effects, such as dizziness, drowsiness, and nausea:

> "Side effects for all opioids include **drowsiness**, impaired judgment, **nausea**, and constipation." (See page 5 of *What are the Specific Drugs and Remedies for Treating a Migraine Attack*, by University of Maryland Medicine, 6/30/02; attached hereto as Exhibit R)(emphasis added).

> "Side effects of opioids include mild **dizziness**, **drowsiness**, sedation and unclear thinking. These make it unsafe for you to drive or operate machinery." (See page 1 of *Opioids (narcotics)*, by Mayo Clinic Staff; Mayo Foundation for Medical Education and Research, Nov. 22, 2002; attached hereto as Exhibit S)(emphasis added).

> "Generally, opioids relieve pain, cause mood fluctuations, alter brain activity, cause **drowsiness**, depress breathing, and **slow digestive functioning**." (See page 1 of *Opioid and Pregnancy*: Beyond the ABCs, by Alberta Alcohol and Drug Abuse Commission; 2002, attached hereto as Exhibit T)(emphasis added).

It is also well-known in the art that Dextromethorphan *free base* shares these untoward side effects:

> "**DEXTROMETHOPHAN SIDE EFFECTS**: **Dizziness**, **drowsiness**, **nauseua**, **vomitting**, or stomach ache may occur the first several days as your body adjusts to the medication.." (See page 1 of *Dextromethorphan - Oral Liquid*, by Drug Information; attached hereto as Exhibit U)(emphasis added).

The art further recognizes that dextromethorphan *hydrobromide* demonstrates the same side effects on the central nervous system and the gastrointestinal tract as those noted above for its *free base*:

> "Side Effects: *CNS*: **Dizziness**, **drowsiness**. *GI*: **N&V**, stomach pain." (See page 1 of *Dextromethorphan hydrobromide*, by Healthdigest.org; attached hereto as Exhibit V)(emphasis added).

The Examiner, having distorted an isolated teaching in Chopdekar (an irrelevant and erroneous *antihistamine* reference) argues that the artisan would have been motivated to use the tannate salt owing to expectations of reduced side effects. The art however contradicts that argument by yet *further* recognizing that dextromethorphan tannate plagues patients with the *same* "Adverse Effects" that are incidental to the use of dextromethorphan hydrobromide:

> "Adverse Effects....**gastrointestinal upset**, **drowsiness**, **dizziness**" (See *Drug Monograph Tananfed DMX™ Suspension*, by Peery, Pharm.D, for Missouri Medicaid; 2/19/03; attached hereto as Exhibit W)(the adverse effects of the product's 25 mg. / 5ml. suspension dextromethorphan **tannate** component) (emphasis added).

Accordingly, contrary to the Examiner's assertion, the artisan would **not** have expected that preferring a *tannate* salt to any other salt would "reduce" the side effects inherent to any free base active ingredient. In a nutshell, dextromethorphan HBr is a fast-releasing opioid, that is

specifically *contraindicated* for asthma and for the wet, mucous-producing coughs that attend bronchitis and the common cold, therefore it is **not** the functional equivalent of carbetapentane tannate, insofar as carbetapentane tannate is a slow releasing non-opioid, instantly-claimed for treating cough associated with each of asthma, bronchitis, and the common cold. Moreover, both the Federal Circuit's predecessor court and the Board of Patent Appeals and Interferences have stated that functional equivalence is not the test for obviousness:

> "**We disagree with the supposed logic of the Patent Office position. The examiner and the board appear to hold the mere existence of 'functional and mechanical equivalence' establishes 'obviousness.' We think this involves a non-sequitur. Expedients which are functionally equivalent to each other are not necessarily obvious in view of one another**. The statutory mandate of 35 U.S. C. §103 is that the claimed subject matter be unobvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." Application of Scott, 51 C.C.P.A. 747, 751 (CCPA 1963)(emphasis added).
>
> "The Examiner's rejection fails to establish a prima facie case of obviousness. **Functional equivalence and the solution to specific problems are not, per se, the appropriate determinants of obviousness**. Ex parte Gibson, 2002 WL 1801330, *4 (Bd. Pat. Apps. & Interf.)(emphasis added).

Therefore, the Examiner's motivation arguments have been traversed, and the claims are not obvious in view of the references.[2]

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[2] Moreover, the art suggests that the inclusion of tannins (from which tannates are derived) may actually interfere with some of the cough agents noted in Kupper—dextromethorphan ("Cardec DM ") among them:

> "Tannins may interfere with the absorption/effectiveness of alkaline or steroidal medications. **Avoid tannins when using** Atropine, **Cardec DM**, **Codeine**, **Ephedrine** and **Pseudoephedrine**, Lomotil/Lonox, Loop Diuretics, Spironolactone, Theophylline/Aminophylli, Thiazide Diuretics, Triamterene. This is not an exhaustive list." (See page 1 of *Intensive Nutrition Incorporated*; attached hereto as Exhibit X)(emphasis added).
>
> "**Herbs with large amounts of tannins may interfere with the absorption of codeine and should not be taken together with codeine or codeine-containing products**." (see Kroger Pharmacy & Health Health guide; attached hereto as Exhibit Y)(emphasis added).

IV. The Pending Claims Are Not Obvious Over Kupper By Itself, Nor In View Of Chopdekar in Further view of Sims.

To the extent the Examiner repeated the same arguments to support the continued application of Kupper and Chopdekar, Applicants repeat the earlier-made arguments in traverse thereof.

The Examiner concedes *only* that Kupper and Chopdekar do not teach the dosage range of the *antitussive*. In fact, however, Kupper and Chopdekar fail to teach or suggest the claimed ranges or the claimed amounts of *either* carbetapentane tannate or guaifenesin. The syrup of Kupper's *Example II* merely discloses that the dextromethorphan HBr and guaifenesin are present in a 1:10 ratio by "Weight %," it does not does not teach or suggest the milligrams per tablet and milligrams per 5 ml. of suspension, of actives, as instantly claimed. Notably, in the preferred embodiment of the instantly claimed *suspension*, the ratio of the carbetapentane tannate antitussive to the guaifenesin expectorant is less than 1:4—further undermining the Examiner's functional equivalency arguments regarding dextromethorphan and carbetapentane.

The Examiner cites Sims, which is directed to *Ibuprofen-Antitussive Combinations*, with an optionally-included expectorant. Sims teaches Markush groups of antitussives and expectorants that include carbetapentane and guaifenesin respectively, and a limitless suggestion of salts, tannates being specifically mentioned. The Examiner asserts that Sims teaches that "[t]he antitussive is utilized in the amount of 1-50 mg depending on the specific antitussive used and the expectorant in the amount of 100-1000 mg." The Examiner further asserts that "Sims teaches this is the suitable and conventional range of the cough agents in cold remedy formulations," and concludes that it would have been obvious "to look to Sims teachings and utilize the instant dosage ranges."

The Examiner again ignores Sims *as a whole* and takes tremendous editorial license with

select statements within Sims to support her conclusions. With regard to active ingredient amounts, Sims offers that:

> "The antitussive employed herein is selected from codeine, hydrocodone, carbetapentane, caramiphen, and dextromethorphan, or a therapeutically active stereoisomer thereof substantially free of its other stereoisomers, or a pharmaceutically acceptable salt thereof.
>
> The amount of antitussive useful in the practice of the present invention may vary from about 1 mg to 50 mg depending on the specific antitussive. **The amount of a salt such as codeine phosphate is determined based on the amount of antitussive contained therein**. The amount of expectorant useful in the practice of the present invention may vary from about 100 mg to 1000 mg per daily dosage." (col. 3, lines 24-39, emphasis added).

First, Applicants note that the instant claims do not recite ranges or amounts directed to an antitussive *free base*—to which Sims 1-50 mg. range might speak—but rather are directed to an antitussive *salt*—to which Sims offers *no* instructive range or amount:

> "**The amount of a salt such as codeine phosphate is determined based on the amount of antitussive contained therein**." (Sim, col. 3, lines 33-35, emphasis added).

The Examiner selectively edits this portion of the Sims paragraph out of her motivation statement, because it would clearly undermine her ability to apply Sims' 1-50 mg. antitussive *free base* range teaching to the antitussive *salt* ranges and amounts aspects of the instant claims. The unlimited salt components mentioned in Sims range from the lowest molecular weight inorganic hydrobromides and hydrochlorides to the most massive and complex of organics, such as the here-at-issue tannic acid (mol. weight 1700). Insofar as the antitussive free bases recited in Sims are equally as expansive in chemical complexity and weight, the artisan would not be the least bit guided toward the instantly-claimed carbetapentane tannate ranges and amounts, by Sims' vague 1-50 mg. antitussive free base range teaching.

Second, Applicants note that nowhere in Sims does it state that the 1-50 mg. antitussive range and the 100-1000 mg. expectorant range are the "suitable and conventional range[s] of the

cough agents in cold remedy formulations;" the Examiner has made this up—the words "suitable" and "conventional" don't even appear in Sims. What *does* appear in Sims however, and what has already been argued at length, is that *the whole* of Sims is directed to teaching the artisan that it is desirable to combine an analgesic with an antitussive. More specifically, Sims teaches the artisan that it is desirable to combine the S-enantiomer of ibuprofen with one of several specific *antitussives*. The desirability of that combination is clear from Sims' laudatory rhetoric regarding the improved pain relief advantages that ibuprofen's *S*-enantiomer brings to antitussive combinations, over racemic ibuprofen formulations:

> "The utilization of (S)-ibuprofen in an analgesic/antitussive combination offers significant advantages over the combination of racemic ibuprofen with an antitussive. (S)-ibuprofen provides a faster onset of pain relief and an enhanced degree of relief compared to racemic ibuprofen. These benefits are increased in an (S)-ibuprofen/antitussive combination as **the antitussive may potentiate the action of the (S)-ibuprofen**. This has not heretofore been observed because the art has not proposed the combination of the (S)-ibuprofen enantiomer, absent (R)-ibuprofen, with an antitussive. **Furthermore the antitussive also may potentiate the duration of the analgesic and anti-inflammatory response. The presence of the (R)-ibuprofen may blur the potentiated effect**." [3] (column 2, lines 46-59, emphasis added).

Clearly, the 1-50 mg. antitussive range that Sims discloses would, if suggestive of anything at all, guide the artisan *only* in his efforts to "potentiate" and enhance the analgesic effects of S-ibuprofen. It is **not** directed to ranges that the artisan would rely upon, with a reasonable expectation of success in his efforts to formulate a cough / cold composition, as claimed in claims 15-22. Much less would he rely on them for guidance in formulating the twice-a-day methods recited in new Claims 31-34, since Sims offer no indication that the 1-50 mg. antititussive range is a daily dose, but rather only suggests that it is an (S)-ibuprofen potentiating

[3] In other words, Sims teaches that presence of the (R)-ibuprofen enantiomer diminishes the synergy of his invention. This Sims teaching is worth noting because it *further* contradicts the earlier-traversed Examiner arguments concerning expectations of an "additive effect" upon combining known cough agents.

dose.

With regard to the 100-1000 mg. expectorant range cited in Sims, the artisan would consider this vague disclosure to be equally lacking in guidance with regard to the instant claims. It is debated in the art that the dosage of any given expectorant that is necessary to *effectively* induce mucolytic activity varies widely among expectorants. It is also debated in the art that those ranges of expectorants *conventionally* used, even those ranges *conventionally* used for guaifenesin, and thought to be effective, might not be effective in those *conventionally* used ranges at all:

> "*Expectorants*: Expectorants increase bronchial mucus secretion, resulting in increased liquefaction of the sputum, which can then be coughed up. How effective they are is debatable, but they are popular remedies. The main expectorant ingredients include guaifenesin, ammonium salts and ipecacuanha. **The dose of guaifenesin is worth highlighting in that the amount required to produce expectoration is 100-200 mg, and not all products contain a sufficiently high dose. Other traditional expectorants include squill, creosote, menthol and citric acid, but they are probably too weak to be effective in the doses used.**" (See page 613 of Exhibit E).

Accordingly, the artisan would not be guided to the instantly-claimed range of guaifenesin by Sims' debatable and expectorant-inspecific disclosure of a 100-1000 mg. expectorant range. And to the extent that that debatable 100-1000 mg. range is directed to a "daily dosage," much less would the artisan be guided to the guaifenesin ranges and amounts recited in the twice-a-day aspects of new Claims 31-34. Lesser still would he be guided to the instant guaifenesin ranges or amounts in combination with the multitude of other elements presently claimed.

The rejections are accordingly traversed, and the references, whether considered alone or collectively, do not teach or suggest the basic carbetapentane tannate and guaifenesin combination. Nor do the references teach or suggest that active ingredient combination in tablet or suspension forms, in further combination with the ranges, amounts, or BID dosing elements

that further define the additional embodiments of the instantly claimed invention.

In view of the foregoing, Applicants submit that the claims are patentable in view of the cited references. As the application is in all respects in condition for allowance, Applicants request its prompt passage to issue.

It is believed that no fee is due. However, if any fee is due it should be charged to Deposit Account No.: 03-0678.

CERTIFICATE OF MAILING

Deposit Date: November 24, 2004

I hereby certify that this paper and the attachments hereto are being deposited today with the U.S. Postal Service with sufficient postage as First Class Mail to Addressee, under 37 CFR 1.8, on the date indicated above addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

11/24/04

Raymond E. Stauffer, Esq. Date

#224572 v3 - response to FINAL office action

Respectfully submitted,

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OVER-THE-COUNTER TREATMENT OF COUGHS AND COLDS

By Pamela Mason, PhD, MRPharmS

In this month's special feature, the author offers some timely revision of the different types of cough and cold remedies available over the counter and provides advice on when patients should be referred to their general practitioner

Cough is a common symptom that can be caused by a variety of conditions. It can be classified as either acute (ie, the cough lasts for two weeks or less) or chronic (ie, the cough last for longer than that).

Acute cough is generally caused by viral infections of the upper respiratory tract and, although less common, it can be caused by more serious conditions such as pulmonary embolism and pneumonia.

Chronic cough is often a symptom of post-nasal drip syndrome, which is secondary to a cold, sinusitis, bronchitis, asthma, gastro-oesophageal reflux disease or congestive heart failure. Patients with lung disorders such as asthma, emphysema, lung cancer and tuberculosis may also have chronic cough as, of course, may smokers. Angiotensin-converting enzyme (ACE) inhibitors can cause a dry, persistent cough in up to 10 per cent of patients, although angiotensin-II receptor antagonists (eg, losartan, valsartan) do not appear to do this.

The most common cause of cough in children is a viral or bacterial respiratory infection. In most cases, such infections are self-limiting although they can give rise to more serious conditions such as croup, in which the cough has a harsh, barking nature, and also whooping cough. Both croup and whooping cough are associated with difficulties in breathing and require referral to a doctor. More rarely, cough in children may be a symptom of heart disease, foreign body aspiration, aspiration caused by poor co-ordination of sucking and swallowing or oesophageal motility disorders.

Physiologically, cough is a vital defensive reflex, which is stimulated by irritation of the respiratory mucosa in the lungs, the trachea or pharynx and co-ordinated by the central cough centre of the medulla. It starts with a deep inspiration followed by closure of the glottis then forceful contraction of the chest wall, abdominal wall and muscles of the diaphragm against the closed glottis. When the glottis opens, mucus, cellular debris and foreign material from the respiratory tract are propelled at high speed.

Symptoms Coughs are described as either productive (ie, chesty, producing sputum) or non-productive (ie, dry, with no sputum).

A productive cough should be encouraged because it enables the expulsion of secretions from the lower respiratory tract that, if retained, could impair breathing and the ability of the lungs to resist infection. The appearance of the sputum can be useful for assessing the severity of any underlying disease. Clear secretions are generally uninfected and of little significance, unless produced in copious amounts, which may occur in disorders of allergic origin, including asthma. Thick yellow, green or rusty-coloured secretions or malodorous sputum may indicate a chest infection, such as bronchitis or pneumonia. Blood in the sputum (haemoptysis) may give rise to a colour ranging from pink to deep red. This may be the result of a relatively minor problem, such as a burst capillary following a bout of violent coughing or may be a sign of a more serious condition, such as lung cancer, heart failure, pulmonary embolism or tuberculosis.

A non-productive cough serves no useful physiological purpose and is irritating to both the sufferer and those with whom he or she lives and works. Non-productive coughs are generally the result of a viral infection, although asthma, ACE inhibitors and lung cancer are possible causes.

Management Management of cough depends on the age of the individual, symptoms and likely causes. Headings intended as an aide-memoire for pharmacists assessing cough sufferers are shown in Panel 1. Having acquired a history of the patient's present symptoms, the pharmacist can then go on to discuss management. In some cases, this may mean referral to a doctor (Panel 2).

The effectiveness of over-the-counter cough remedies has often been questioned, particularly those with sub-therapeutic dos-

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es of active ingredients and those with apparently contradictory ingredients. However, people who visit the pharmacy with a cough want relief of symptoms and, although the value of cough remedies remains unproven, the role of the placebo effect should not be forgotten.

Choice of product depends on the type of cough. Non-productive coughs should be treated with a cough suppressant and productive coughs with an expectorant. Productive coughs should not be treated with cough suppressants and the combination of expectorants and suppressants found in some remedies is illogical.

Cough suppressants There are three main categories of cough suppressants: those that are centrally acting, demulcents and antihistamines.

Centrally acting cough suppressants (eg, pholcodine, codeine and dextromethorphan) act on the cough centre in the brain and reduce the discharge of nerve impulses to the muscles that cause coughing. All can, in theory, cause sedation, but pholcodine and dextromethorphan produce fewer adverse effects than codeine and are thought to have a lower abuse potential. In addition, codeine is not suitable for children, although both pholcodine and dextromethorphan can be given to children over 2 years of age.

Demulcents such as simple linctus and glycerin, lemon and honey, soothe and coat the pharynx. They have a pleasant taste and are particularly suitable for children and pregnant women because of their lack of active ingredients.

Antihistamines used in cough mixtures include diphenhydramine, promethazine and triprolidine. These act as cough suppressants, not by virtue of their action on histamine, but by reducing cholinergic transmission of nerve impulses in the cough reflex. In theory, they reduce the frequency of coughing and also dry up secretions, making them useful when a cough and cold occur together. Their sedative effect is valuable if the cough is disturbing sleep. Products containing sedative antihistamines are best avoided by people taking other sedative medicines (eg, anxiolytics, hypnotics) and also by patients with narrow-angle glaucoma or prostatic hypertrophy.

Expectorants Expectorants increase bronchial mucus secretion, resulting in increased liquefaction of the sputum, which can then be coughed up. How effective they are is debatable, but they are popular remedies. The main expectorant ingredients include guaifenesin, ammonium salts and ipecacuanha. The dose of guaifenesin is worth highlighting in that the amount required to produce expectoration is 100–200mg, and not all products contain a sufficiently high dose. Other traditional expectorants include squill, creosote, menthol and citric acid, but they are probably too weak to be effective in the doses used.

Panel 1: Coughs — assessment of the patient

Age In children, a common cause of cough is colds and catarrh. Parents should be reassured that episodes of this nature are usually self-limiting and antibiotics are not necessary. Pharmacists should take care to exclude croup, whooping cough and asthma and other causes of cough in children. In adults over 40, especially smokers, serious lung disorders (eg, cancer, emphysema, chronic bronchitis) should be considered. In cases of self-limiting cough, the age of the sufferer (ie, child or adult) will influence the choice of treatment.

Duration and frequency Most coughs are self-limiting and will get better in a few days with or without treatment. Coughs lasting longer than two weeks should be referred.

Onset Most coughs start gradually, although in the case of pneumonia, onset can be sudden and acute, causing collapse. Coughs tend to be worse at night, but in children care should be taken to identify dry night-time coughs, which could be due to asthma. Night-time cough and breathlessness in adults can be due to pulmonary congestion as found in heart failure.

Type of cough Is the cough productive or non-productive?

Characteristics of sputum Is the sputum clear or coloured? Does it have a bad smell?

Accompanying symptoms Coughs are often associated with a cold, sore throat, nasal congestion and a high temperature. Such symptoms would indicate a viral infection. Symptoms such as shortness of breath, chest pain and weight loss could indicate more serious disease. A painful calf, possibly associated with swelling in the calf or ankle, may be caused by deep vein thrombosis. The thrombus may break up and travel to the lungs where it will lodge as a pulmonary embolus. This may result in cough alongside the more common symptoms of chest pain and shortness of breath.

Smoking habit Many smokers suffer from persistent cough, but it is important to check whether the nature of the cough has changed, which might indicate a more serious condition.

Previous history Check whether there is a history of heart disease (cough can be a symptom of heart failure), gastro-oesophageal reflux disease (GORD can cause coughing), asthma or chronic bronchitis. Patients with diabetes may prefer a sugar-free cough mixture, although the amount of sugar in cough medicines is unimportant when used for short periods, eg, five days.

Medication ACE inhibitors can cause cough.

Adapted from Blenkinsopp A, Paxton P. Symptoms in the pharmacy. A guide to the management of common illness. 3rd edition, 1998, Pp23–26, and Edwards C, Stillman P. Minor illness or major disease. 3rd edition, 2000, Pp19–21

Bronchodilators Sympathomimetics, such as ephedrine and pseudoephedrine, are included in cough medicines for their bronchodilatory and decongestant actions. They can be useful if a person has a blocked nose as well as a cough, and combination products containing a bronchodilator/decongestant with either a cough suppressant or an expectorant (but not both) are logical.

Because they can raise blood pressure, sympathomimetics should be avoided by those with cardiovascular disease (including hypertension) and by those taking monoamine oxidase inhibitors (MAOIs) or beta-blockers. They should also be avoided in patients with hyperthyroidism or diabetes mellitus.

Theophylline is also included in some OTC preparations for its bronchodilatory effect, but the dose is likely to be sub-therapeutic for most adults. Theophylline interacts with several other drugs, including carbamazepine, cimetidine, erythromycin, 4-quinolones, phenytoin and rifampicin. It is important to check that a person is not taking theophylline on prescription because the effect with an OTC preparation will be additive.

COLDS

The common cold is a self-limiting viral infection of the upper respiratory tract. The highest incidence is in young children, who typically have five to seven colds a year, but may have more, particularly if they attend day care. Adults typically have two or three colds a year, but may have more if they live with or frequently encounter young children.

Signs and symptoms of the common cold typically appear one to three days after infection, lasting for a few days and usually not longer than two weeks. The possibility of allergic rhinitis should be considered

Panel 2: Coughs — when to refer

- Coughs of longer than two weeks duration
- Sputum is coloured green, rusty-brown or yellow, or is blood stained or foul smelling
- Chest pain — may be due to a respiratory cause, eg, pleurisy, a pulmonary embolus, straining the muscles from coughing, or a non-respiratory cause, eg, heartburn, anxiety, angina, heart attack
- Shortness of breath — may be a symptom of a cardiac disorder, eg, heart failure, or a respiratory disorder, eg, asthma, chronic bronchitis, emphysema
- Wheezing
- Recurrent night-time cough
- Whooping cough or croup
- A worsening smokers' cough
- Suspected adverse drug reaction, eg, ACE inhibitors
- Any concurrent condition where infection may be a risk, eg, heart failure, chronic respiratory conditions, immunosuppression
- Weight loss, particularly in patients over the age of 40 years
- Feeling generally unwell, persistent sweating or persistent fever

Adapted from Blenkinsopp A, Paxton P. Symptoms in the pharmacy. A guide to the management of common illness. 3rd edition, 1998, p26, and Edwards C, Stillman P. Minor illness or major disease. 3rd edition, 2000, p28

when symptoms persist beyond this time. In the case of a cold, sore throat is usually the first symptom to appear, followed by runny nose, sneezing, nasal congestion and cough. Headache and sinusitis may also be experienced due to inflammation and congestion of the nasal passages and sinuses. Earache is a common complication of colds, particularly in children. Conjunctivitis may occur but is more commonly a symptom of hay fever.

Colds and influenza are often difficult to tell apart, but influenza tends to start more rapidly than a cold. Early symptoms of 'flu include hot and cold shivering, muscular aches and pains in the limbs, a high temperature, dry sore throat and cough. A period of general malaise and weakness often follows the worst of the symptoms, and a cough may persist for some time in the aftermath of either a cold or 'flu.

Management Sufferers of the common cold should be advised to take aspirin (not for a child under 16 years, see Panel 3) or paracetamol and drink plenty of fluids. A high intake of fluid counteracts excessive fluid loss caused by fever, maintaining adequate hydration of the body in general and of the mucous membranes. Patients with coughs and colds should be advised to increase their fluid intake by around two litres a day.

Steam inhalations also help to provide hydration of the tissues of the upper respiratory tract, diluting the mucus, reducing nasal congestion and soothing the air passages. They are particularly useful if a productive cough is also present. There is no evidence that addition of medication, eg, menthol and eucalyptus or Friar's balsam, has any benefit over water alone, but some people like to use these preparations. A 5ml spoon of inhalant should be added to one pint of hot (not boiling) water and the steam inhaled.

There are a large number of OTC cold remedies, and although they can help to make the sufferer feel better, care should be taken to ask questions about prescribed and other OTC medicines because of the risk of interactions. In addition, individuals may wish to use more than one product for their cold and care should be taken to ensure that overdose of ingredients such as paracetamol does not occur. The pharmacist has an important role in taking a medication history, asking questions about the symptoms and helping the sufferer to select the most appropriate remedy.

Decongestants Sympathomimetic decongestants are used in cold remedies to constrict the swollen mucosae and dilated blood vessels of the nasal passages. This leads to improvement in the drainage of mucus and circulation of air and relief of nasal stuffiness. The compounds used in oral decongestant preparations for colds are the same as those in cough medicines, plus phenylephrine and phenylpropanolamine, and the same cautions and drug interactions apply.

Studies have shown that phenylpropanolamine, in particular, can increase the blood pressure of young, normotensive people, although this has generally occurred in doses above those recommended for use as a decongestant. The Committee on Safety of Medicines has issued a reminder in relation to phenylpropanolamine that it should not be taken by patients with heart disease or high blood pressure and by those taking MAOIs (see the British National Formulary section 3.10).

Decongestants can also be applied topically in the form of sprays or drops. Ephedrine and phenylephrine are relatively short acting and need to be used every three to four hours. Oxymetazoline and xylometazoline are longer lasting (up to eight hours) and need to be used only two or three times a day. The use of local decongestants is associated with rebound congestion (rhinitis medicamentosa), although the longer-acting compounds take longer to produce this effect than the shorter acting ones. To prevent this complication, none of these preparations should be used for more than seven days.

Antihistamines Antihistamines are used in cold remedies because they suppress the production of mucus, providing relief for runny nose and preventing the postnasal drip that irritates the throat and causes coughing.

Vitamin C Vitamin C has been promoted for prevention of the common cold, but evidence of its efficacy is controversial. Large doses (1–2g) may help to reduce the symptoms of a cold if taken as soon as the first symptoms appear, but there is little evidence that vitamin C can prevent colds.

Zinc There is some evidence that zinc lozenges (providing 13–23mg zinc) may reduce the severity and duration of cold symptoms. Zinc is believed to work by combining with the rhinovirus coating to prevent the virus entering cells and reproducing further.

Panel 3: Aspirin use in children under 16 years of age

The Committee on Safety of Medicines has issued new advice on the use of aspirin in children (*PJ*, 26 October, p593). It now recommends that aspirin should not be given to children under the age of 16 unless specifically on the advice of a doctor. The advice is intended to reduce further the incidence of Reye's syndrome, which can be associated with aspirin use in children.

BSHP

The British Society for the History of Pharmacy, founded in 1967, aims to promote historical research related to pharmacy and to publish research work and other items of interest in its quarterly journal, the *Pharmaceutical Historian*. The society holds meetings and an annual conference and organises visits to places of pharmaceutical interest. Further information is available from the society's website (www.bshp.org).

Membership of the society is open to individuals for an annual subscription of £20. Non-pharmacist members are welcome. Special subscription rates are available for overseas and corporate membership.

All inquiries concerning membership, subscriptions or the society's activities should be addressed to the British Society for the History of Pharmacy, 840 Melton Road, Thurmaston, Leicester LE4 8BN (tel 0116 264 0083; fax 0116 264 0141; e-mail bshp@associationhq.org.uk).

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EXPECTORANT

Prescription Drugs Non-Prescription Drugs

Expectorants are drugs that loosen and clear mucus and phlegm from the respiratory tract.

Purpose

The drug described here, Guaifenesin, is a common ingredient in cough medicines. It is classified as an expectorant, a medicine that helps clear mucus and other secretions from the respiratory tract. However, some debate exists about how effectively Guaifenesin does this. In addition, some cough medicines contain other ingredients that may cancel out Guaifenesin's effects. Cough Suppressants such as Codeine, for example, work against Guaifenesin because they discourage coughing up the secretions that the expectorant loosens.

There are other ways to loosen and clear the respiratory secretions associated with colds. These include using a humidifier and drinking 6-8 glasses of water a day.

Description

Guaifenesin is an ingredient in many cough medicines, such as anti–Tuss, Dristan Cold & Cough, Guaifed, GuaiCough, and some Robitussin products. Some products that contain Guaifenesin are available only with a physician's prescription; others can be bought without a prescription. They come in several forms, including capsules, tablets, and liquids.

Prescription Drugs Non-Prescription Drugs

TRINITY EPISCOPAL CHURCH
SANTA BARBARA, CA

Trinity Health

Home/Trinity Health Main Page/Cold Season

It's Cold Season Again!

By Michelle Arya, RN Parish Nurse

Every year we are exposed to any number of the over 200 viruses that cause the common cold. The well-known symptoms include head congestion, sore throat, coughing, fever, headache, restlessness, sneezing, watery eyes, and aches and pains. Most colds clear up on their own in a week to ten days, but occasionally can lead to more serious illnesses such as bronchitis, pneumonia, or flu. Many of us get colds more often than the usual once or twice a year, which may be a sign that our immune systems are not working efficiently. Since there is no cure for the common cold, the best approach is prevention. Once a cold has a firm grip on you, it's hard to stop it or shorten its course. You can, in a sense, catch a cold from yourself. When your immune system weakens from factors such as stress and/or a poor diet, viruses can take hold. Here are some ideas to help you prevent and/or treat a cold.

1. Increase your water intake, (notice I didn't say "fluids;" this is because many fluids will decrease the efficiency of your immune system, such as any that contain caffeine or sugar). Don't replace water with other fluids, but you can add to the fluid intake with diluted fruit juices, broth, or herbal teas.

2. Decrease or eliminate sugar from your diet, as it has been shown to actually sedate the white blood cells for hours at a time, thus eliminating the function of fighting off infection.

3. Be sure to eat a wide variety of fruits and vegetables on a regular basis. A good way to be sure you're getting the right ones is to try and eat as many different colored fruits and vegetables as possible every day.

4. At the first sign of a cold, use alcohol-free echinacea with goldenseal to boost the immune system, but it is not recommended that these be taken on a daily basis all the time. Sucking on zinc lozenges at the first signs of a sore throat can also give you an immunity boost. Split the doses of all of these throughout the day. With zinc, don't exceed 100 mg. per day.

5. When you have a cold, avoid dairy products and orange juice as they both can significantly increase mucus production. Do take extra vitamin C, spreading the doses throughout the day. Other fruit juices are OK, but dilute them with water to avoid sugar overload.

The Soft Drink Trap

7. Most over-the-counter cold remedies contain some combination of acetaminophen and various decongestants, antihistamines and cough suppressants. Some experts believe that these ingredients may actually work against each other. For example acetaminophen may increase nasal congestion while the decongestant decreases it. If a cold is making you extremely uncomfortable, and you feel you must take something for it, it is better to take a single ingredient product appropriate for the particular symptom you are treating.

8. Wash your hands often. Cold viruses can survive for several hours on hands, tissues, and hard surfaces. Avoid shaking hands with or hugging others while you are sick and especially in the first several days of symptoms.

9. Do not give aspirin or any product containing aspirin to a child with any symptoms of a viral infection, including a cold. This can cause a very serious disease called Reyes Syndrome.

10. Antibiotics are ineffective against viral infections, but many people still ask their doctors to prescribe them. Antibiotics work only against bacterial infections such as strep throat-- not viral infections. In fact, because antibiotics kill off "good" bacteria with the bad, antibiotics actually inhibit the body's efforts to defend itself against viral infection.

11. If congestion develops in the chest, it is best to consult a physician as chest (lung) infections can be quite serious. Also, contact your healthcare provider if your fever goes above 102 degrees for more than 2 days (for children, call same day), if yellow or white spots appear in the throat, if the lymph nodes under the jaw and in the neck become enlarged, and/or if chills and shortness of breath occur.

There many more nutritional things we can do to build up our immune systems, but these basic guidelines will go a long way towards keeping ourselves and our families healthy.

Information obtained from :

"Prescription for Nutritional Healing" by James and Phyllis Balch, MDs

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Health Corner

Here are few tips to help you through this cold and flu season:

To avoid colds and flu as well as help you get better if you do get sick:

1. Increase your water intake (by a whole lot!). Don't replace water with other fluids that have caffeine or sugar; these will do more damage than good.

2. At the first signs of a cold, use an alcohol-free echinacea and goldenseal combination to boost the immune system, also garlic, which

is a natural antibiotic and immune system enhancer.

3. If you feel a sore throat coming on, suck on zinc lozenges, several per day, divided throughout the day, but don't exceed 100 mg. per day.

4. Decrease or eliminate sugar from your diet: its been shown to sedate white blood cells, which are the infection fighters of your immune system.

5. Avoid dairy products and orange juice when you have a cold; they will increase mucus production. Do take extra vitamin C in divided doses throughout the day. Other fruit juices are OK, but watch the sugar content and go for less sugary or dilute with water. Better yet, go for vegetable juices with a high vitamin C content.

6. Rest.

7. Wash your hands often.

Michelle Arya, RN,
Parish Nurse

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Cough

DESCRIPTION

Certain parts of the respiratory system are naturally sensitive to foreign matter. A cough is usually a reflex to clear the airways. This reflex is essential to life and therefore should only be suppressed with care since it serves a vital function.

Coughs vary from mild to severe, and come in two general forms: productive and nonproductive. Productive coughs are those that produce fluid or mucus, and are often caused by lung Infections. Nonproductive coughs do not bring to the surface fluid or mucus. Persistent coughs are those which last for two or more weeks. If this occurs without other respiratory symptoms, disease of another organ is usually involved.

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HERBS

Black Cohosh
Garlic (1)

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NUTRITIONAL SUPPLEMENTS:

HOMOEOPATHY

If your cough is part of a cold or flu, then it may be better to find a medicine that covers the overall picture of the illness from the "Common Cold" and "Influenza" section.
However, sometimes a cough will persist after the original viral illness

Quick Link
PRINTABLE VERSION
DESCRIPTION
HERBS
NUTRITIONAL SUPPLEMENTS:
HOMOEOPATHY
HOMOEOPATHY: Dry Cough
HOMOEOPATHY: Chesty Coughs
HOMOEOPATHY: Coughing spasms
REFERENCES

has settled, or indeed it may be the only feature of the illness. If so, choose a medicine from the list below.

HOMOEOPATHY: Dry Cough

Aconite
Dry croupy cough especially in cold dry weather.
Worse at night.
Breathing feels difficult.
Better sitting up or lying on back.
Anxiety and restlessness.

Bryonia
Dry, hacking cough.
Worse at night, especially after eating or drinking.
Cough extremely Painful, must splint chest.
Want to breathe deeply, but it hurts.
Thirst for cold drinks.

Hepar sulph.
Hoarse dry cough with choking and gagging.
Triggered by any part of the body getting cold.
Can be croupy or barking.
Small amounts of yellowish phelgm.

HOMOEOPATHY: Chesty Coughs

Ipecac.
Persistent violent cough, little phlegm.
Accompanying nausea and Vomiting.
Very loose, rattly and/or wheezy.

Pulsatilla
Thick yellow loose phlegm.
Loose cough in day, dry at night.
Better in the open air, worse in a stuffy room.

Kali. bich.
Brassy cough.
Large amounts of stringy phlegm which is very glutinous and stick, difficult to bring up.

HOMOEOPATHY: Coughing spasms

Cuprum met.
Exhausting spasms of cough.
Better for sips of cold drink.
Marked spasm and constriction of the chest.

Drosera
Paroxysms of cough like whooping cough, often with retching.
Spasms follow one after another rapidly.
Worse as soon as puts head on pillow or at night.
Speaking aggravates cough.

Ignatia
Dry tickly cough.
Feels as if a constriction in the throat.
Frequent short spasms, no retching.
Often has to suppress the cough by willpower.
Tendency to sigh.

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REFERENCES

1. Elnima EI, et al: The antimicrobial activity of Garlic and onion extracts, Pharmazie, 38(11), Nov 1983, p 747-748.

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Dextromethorphan

Also indexed as: Delsym®, Pertussin®, Robitussin® Cough Calmers, Robitussin® Pediatric Cough, Sucrets® Cough Control Formula, Vicks® Formula 44

Combination drugs: Nyquil®, Nyquil® Hot Therapy Powder, Robitussin® CF, Robitussin® DM, Tylenol® Cold, Tylenol® Multi-Symptom Hot Medication

Dextromethorphan is a cough suppressant used for short-term treatment of nonproductive coughs. It is available in nonprescription products alone and in combination with other nonprescription drugs to treat symptoms of allergy, colds, and upper respiratory infections.

Summary of Interactions with Vitamins, Herbs, and Foods

In some cases, an herb or supplement may appear in more than one category, which may seem contradictory. For clarification, read the full article for details about the summarized interactions.

Depletion or interference	None known
Side effect reduction/prevention	None known
Supportive interaction	None known
Reduced drug absorption/bioavailability	None known
Adverse interaction	None known

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An asterisk (*) next to an item in the summary indicates that the interaction is supported only by weak, fragmentary, and/or contradictory scientific evidence.

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healthnotes

DrugDigest

Brand Name(s): Benylin, Delsym, Pertussin, Robitussin Cough
Generic Name Dextromethorphan

What is dextromethorphan?
DEXTROMETHORPHAN (Benylin®, Delsym®, Pertussin®, Robitussin®) helps to relieve a persistent cough caused by colds or the flu. Do not use dextromethorphan for treatment of a chronic cough that is due to smoking, asthma, emphysema, or problems that cause a large amount of phlegm. Generic dextromethorphan is widely available in a variety of non-prescription medicines, in capsules, lozenges, syrups, extended-release oral suspensions, and chewable tablets.

What should my health care professional know before I take dextromethorphan?

They need to know if you have any of these conditions:
•asthma
•emphysema
•liver disease
•smoker
•an unusual or allergic reaction to dextromethorphan, other medicines, foods, dyes, or preservatives (some combination products contain bromides)
•pregnant or trying to get pregnant
•breast-feeding

How should I take this medicine?
Take dextromethorphan by mouth. Follow the directions on the container. Suck lozenges slowly or allow to dissolve in the mouth; do not swallow whole. For the oral syrup, use a specially marked spoon or container. Ask your pharmacist if you do not have one; household spoons are not always accurate. Take your doses at regular intervals. Do not take your medicine more often than directed.

Contact your pediatrician or health care professional regarding the use of this medicine in children. Special care may be needed.

What if I miss a dose?
If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What drug(s) may interact with dextromethorphan?
•alcohol
•amiodarone
•barbiturates
•certain medicines for mental depression, anxiety, or other mental disturbances
•furazolidone
•medicines known as MAO inhibitors, such as phenelzine (Nardil®), tranylcypromine (Parnate®), isocarboxazid (Marplan®), and selegiline (Carbex®, Eldepryl®)
•linezolid
•quinidine
•sibutramine
•sleeping pills or tranquilizers
•terbinafine

Tell your prescriber or health care professional about all other medicines you are taking, including non-prescription medicines, nutritional supplements, or herbal products. Also tell your prescriber or health care professional if you are a frequent user of drinks with caffeine or alcohol; if you smoke, or if you use illegal drugs. These may affect the way your medicine works. Check with your health care professional before stopping or starting any of your medicines.

What side effects may I notice from taking dextromethorphan?

Side effects that you should report to your prescriber or health care professional as soon as possible:
Rare, but serious side effects include:
•confusion
•excitement, nervousness, restlessness, or irritability
•severe nausea, vomiting
•slurred speech
Children may get the following side effects from an overdose:
•seizures (convulsions)
•shakey movements
•slow or troubled breathing

Side effects that usually do not require medical attention (report to your prescriber or health care professional if they continue or are bothersome):
•dizziness, drowsiness
•fatigue
•nausea, vomiting
•skin rash (not common)
•stomach ache

What should I watch for while taking dextromethorphan?
If you have a fever, skin rash, or persistent headache as well as a cough, see your prescriber or health care professional. Do not treat yourself for a cough for more than 7 days without consulting your prescriber or health care professional.

You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how dextromethorphan affects you. Alcohol can increase the risk of getting drowsy, dizzy or confused. Avoid alcoholic drinks.

Where can I keep my medicine?
Keep out of the reach of children in a container that small children cannot open.

Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F) unless otherwise directed. Protect liquid preparations from light; do not freeze. Throw away any unused medicine after the expiration date.

Available at: www.DrugDigest.org *Last Updated: 05/02/2000*

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Code of Federal Regulations

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Parts 300 to 499

Revised as of April 1, 2004

Food and Drugs

37.5 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(9) *For products containing phenindamine tartrate identified in § 341.12(i).* Adults and children 12 years of age and over: oral dosage is 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(10) *For products containing pheniramine maleate identified in § 341.12(j).* Adults and children 12 years of age and over: oral dosage is 12.5 to 25 milligrams every 4 to 6 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 6.25 to 12.5 milligrams every 4 to 6 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(11) *For products containing pyrilamine maleate identified in § 341.12(k).* Adults and children 12 years of age and over: oral dosage is 25 to 50 milligrams every 6 to 8 hours, not to exceed 200 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 12.5 to 25 milligrams every 6 to 8 hours, not to exceed 100 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(12) *For products containing thonzylamine hydrochloride identified in § 341.12(l).* Adults and children 12 years of age and over: oral dosage is 50 to 100 milligrams every 4 to 6 hours, not to exceed 600 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 25 to 50 milligrams every 4 to 6 hours, not to exceed 300 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(13) *For products containing triprolidine hydrochloride identified in § 341.12(m).* Adults and children 12 years of age and over: oral dosage is 2.5 milligrams every 4 to 6 hours, not to exceed 10 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 1.25 milligrams every 4 to 6 hours, not to exceed 5 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

[57 FR 58374, Dec. 9, 1992, as amended at 59 FR 4218, Jan. 28, 1994; 67 FR 72559, Dec. 6, 2002]

§ 341.74 Labeling of antitussive drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "cough suppressant" or an "antitussive (cough suppressant)."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "Temporarily" (select one of the following: "alleviates," "calms," "controls," "decreases," "quiets," "reduces," "relieves," or "suppresses") "cough due to" (select one of the following: "minor bronchial irritation" or "minor throat and bronchial irritation") (select one of the following: "as may occur with," "associated with," or "occurring with") (select one of the following: "A cold" or "the common cold") "or inhaled irritants."

(2) "Temporarily" (select one of the following: "alleviates," "calms," "controls," "decreases," "quiets," "reduces," "relieves," or "suppresses") "cough" (select one of the following: "as may occur with," "associated with," or "occurring with") (select one of the following: "A cold," "the common cold," or "inhaled irritants").

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**Labeling of antitussive drug
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l," or "inhaled irritants").

(3) In addition to the required information identified in paragraphs (b) (1) and (2) of this section, the labeling of the product may contain any (one or more) of the following statements:

(i) "Cough suppressant which temporarily" (select one of the following: "Alleviates," "controls," "decreases," "reduces," "relieves," or "suppresses") "the impulse to cough."

(ii) "Temporarily helps you cough less."

(iii) "Temporarily helps to" (select one of the following: "Alleviate," "control," "decrease," "reduce," "relieve," or "suppress") "the cough reflex that causes coughing."

(iv) "Temporarily" (select one of the following: "Alleviates," "controls," "decreases," "reduces," "relieves," or "suppresses") "the intensity of coughing."

(v) (Select one of the following: "Alleviates," "Controls," "Decreases," "Reduces," "Relieves," or "Suppresses") (select one of the following: "Cough," "the impulse to cough," or "your cough") "to help you" (select one of the following: "Get to sleep," "sleep," or "rest").

(vi) *For products containing chlophedianol hydrochloride, codeine ingredients, dextromethorphan, or dextromethorphan hydrobromide identified in §341.14(a) (1), (2), (3), and (4).* "Calms the cough control center and relieves coughing."

(vii) *For products containing chlophedianol hydrochloride, dextromethorphan, dextromethorphan hydrobromide, camphor, or menthol identified in §341.14(a) (1), (3), (4) and (b) (1) and (2).* (*a*) "Nonnarcotic cough suppressant for the temporary" (select one of the following: "alleviation," "control," "decrease," "reduction," "relief," or "suppression") "of cough."

(*b*) (Select one of the following: "Alleviates," "Controls," "Decreases," "Reduces," "Relieves," or "Suppresses") "cough impulses without narcotics."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For oral and topical antitussives.* "A persistent cough may be a sign of a serious condition. If cough persists for more than 1 week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor."

(2) *For oral and topical antitussives labeled for adults or for adults and children under 12 years of age.* "Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor."

(3) *For oral and topical antitussives labeled only for children under 12 years of age.* "Do not give this product for persistent or chronic cough such as occurs with asthma or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor."

(4) *Oral antitussives*—(i) *For products containing codeine ingredients identified in §341.14(a)(2).* "May cause or aggravate constipation."

(ii) *For products containing codeine ingredients identified in §341.14(a)(2) when labeled only for adults.* "Do not take this product if you have a chronic pulmonary disease or shortness of breath unless directed by a doctor."

(iii) *For products containing codeine ingredients identified in §341.14(a)(2) when labeled only for children under 12 years of age.* "Do not give this product to children who have a chronic pulmonary disease, shortness of breath, or who are taking other drugs unless directed by a doctor."

(iv) *For products containing codeine ingredients identified in §341.14(a)(2) when labeled for use in adults and children under 12 years of age.* "Adults and children who have a chronic pulmonary disease or shortness of breath, or children who are taking other drugs, should not take this product unless directed by a doctor."

(v) *For products containing dextromethorphan or dextromethorphan hydrobromide as identified in §341.14(a)(3) and (a)(4) when labeled for adults or for adults and children under 12 years of age. Drug interaction precaution.* "Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or

pharmacist before taking this product."

(vi) *For products containing dextromethorphan or dextromethorphan hydrobromide as identified in § 341.14(a)(3) and (a)(4) when labeled only for children under 12 years of age. Drug interaction precaution.* "Do not use in a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product."

(vii) *For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6).* "May cause excitability especially in children."

(viii) *For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6) when labeled only for children under 12 years of age—*(A) "Do not give this product to children who have a breathing problem such as chronic bronchitis, or who have glaucoma, without first consulting the child's doctor."

(B) "May cause marked drowsiness. Sedatives and tranquilizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives or tranquilizers, without first consulting the child's doctor."

(C) "Do not use [bullet][1] with any other product containing diphenhydramine, even one used on skin".

(ix) *For products containing diphenhydramine citrate or diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6) when labeled for use in adults and children under 12 years of age—*(A) "Do not take this product, unless directed by a doctor, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland."

(B) "May cause marked drowsiness; alcohol, sedatives, and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages while taking this product. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Use caution when driving a motor vehicle or operating machinery."

(C) "Do not use [bullet] with any other product containing diphenhydramine, even one used on skin".

(5) *Topical antitussives*—(i) *For products containing camphor or menthol identified in § 341.14(b) (1) and (2) in a suitable ointment vehicle.* "For external use only. Do not take by mouth or place in nostrils."

(ii) *For products containing camphor or menthol identified in § 341.14(b) (1) and (2) for steam inhalation use.* "For steam inhalation only. Do not take by mouth."

(iii) *For any product containing camphor or menthol in a suitable ointment vehicle or for steam inhalation use and meets the definition of one of the signal words ("extremely flammable," "flammable," "combustible") as described in 16 CFR 1500.3(b)(10).* The labeling contains the appropriate flammability signal word(s) followed by a colon and the statement "Keep away from fire or flame."

(iv) *For any product containing camphor or menthol in a suitable ointment vehicle and that does not contain a flammability signal word as described in 16 CFR 1500.3(b)(10).* "When using this product, do not [bullet][1] heat [bullet] microwave [bullet] add to hot water or any container where heating water. May cause splattering and result in burns." [Information highlighted in bold type.]

(v) *For any product containing camphor or menthol in a suitable ointment vehicle and that contains a flammability signal word as described in 16 CFR 1500.3(b)(10).* "When using this product, do not [bullet] heat [bullet] microwave [bullet] use near an open flame [bullet] add to hot water or any container where heating water. May cause splattering and result in burns." [Information highlighted in bold type.]

(vi) *For any product containing camphor or menthol for steam inhalation use.*

[1] See § 201.66(b)(4) of this chapter for definition of bullet symbol.

[1] For a definition of the term "bullet," see § 201.66(b)(4) of this chapter.

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(d) *Directions.* The
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(ii) *For products con
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nthol for steam inhalation use.*

finition of the term "bullet," see
of this chapter.

"When using this product, do not [bullet] heat [bullet] microwave [bullet] use near an open flame [bullet] add to hot water or any container where heating water except when adding to cold water only in a hot steam vaporizer. May cause splattering and result in burns." [Information highlighted in bold type.]

(vii) *For any product formulated in a volatile vehicle.* The labeling contains the following statement under the heading "Other information": "Close container tightly and store at room temperature away from heat."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *Oral antitussives*—(i) *For products containing chlophedianol hydrochloride identified in § 341.14(a)(1).* Adults and children 12 years of age and over: Oral dosage is 25 milligrams every 6 to 8 hours, not to exceed 100 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 12.5 milligrams every 6 to 8 hours, not to exceed 50 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor.

(ii) *For products containing codeine ingredients identified in § 341.14(a)(2).* Adults and children 12 years of age and over: Oral dosage is 10 to 20 milligrams every 4 to 6 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 to 6 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: Consult a doctor. A special measuring device should be used to give an accurate dose of this product to children under 6 years of age. Giving a higher dose than recommended by a doctor could result in serious side effects for your child.

(iii) *For products containing dextromethorphan or dextromethorphan hydrobromide identified in § 341.14(a) (3) and (4).* The dosage is equivalent to dextromethorphan hydrobromide. Adults and children 12 years of age and over: Oral dosage is 10 to 20 milligrams every 4 hours or 30 milligrams every 6 to 8 hours, not to exceed 120 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: Oral dosage is 5 to 10 milligrams every 4 hours or 15 milligrams every 6 to 8 hours, not to exceed 60 milligrams in 24 hours, or as directed by a doctor. Children 2 to under 6 years of age: Oral dosage is 2.5 to 5 milligrams every 4 hours or 7.5 milligrams every 6 to 8 hours, not to exceed 30 milligrams in 24 hours, or as directed by a doctor. Children under 2 years of age: Consult a doctor.

(iv) *For products containing diphenhydramine citrate identified in § 341.14(a)(5).* Adults and children 12 years of age and over: oral dosage is 38 milligrams every 4 hours, not to exceed 228 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 19 milligrams every 4 hours, not to exceed 114 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(v) *For products containing diphenhydramine hydrochloride identified in § 341.14(a)(6).* Adults and children 12 years of age and over: oral dosage is 25 milligrams every 4 hours, not to exceed 150 milligrams in 24 hours, or as directed by a doctor. Children 6 to under 12 years of age: oral dosage is 12.5 milligrams every 4 hours, not to exceed 75 milligrams in 24 hours, or as directed by a doctor. Children under 6 years of age: consult a doctor.

(2) *Topical antitussives*—(i) *For products containing camphor identified in § 341.14(b)(1) in a suitable ointment vehicle.* The product contains 4.7 to 5.3 percent camphor. "[bullet] see important warnings under 'When using this product' " [appears as the first statement under the heading "Directions" and is highlighted in bold type] [bullet] adults and children 2 years and older: [bullet] rub on the throat and chest in a thick layer [bullet] cover with a warm, dry cloth if desired [bullet] clothing should be loose about throat and chest to help vapors reach the nose and mouth [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(ii) *For products containing menthol identified in § 341.14(b)(2) in a suitable ointment vehicle.* The product contains 2.6 to 2.8 percent menthol. "[bullet] see

important warnings under 'When using this product' " [appears as the first statement under the heading "Directions" and is highlighted in bold type] [bullet] adults and children 2 years and older: [bullet] rub on the throat and chest in a thick layer [bullet] cover with a warm, dry cloth if desired [bullet] clothing should be loose about throat and chest to help vapors reach the nose and mouth [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(iii) *For products containing menthol identified in § 341.14(b)(2) in a lozenge.* The product contains 5 to 10 milligrams menthol. Adults and children 2 to under 12 years of age: Allow lozenge to dissolve slowly in the mouth. May be repeated every hour as needed or as directed by a doctor. Children under 2 years of age: Consult a doctor.

(iv) *For products containing camphor identified in § 341.14(b)(1) for steam inhalation use.* The product contains 6.2 percent camphor. "[bullet] see important warnings under 'When using this product' " [appears as the first statement under the heading "Directions" and is highlighted in bold type] [bullet] adults and children 2 years and older: (select one of the following, as appropriate: *For products formulated to be added directly to cold water inside a hot steam vaporizer.* [bullet] use 1 tablespoonful of solution for each quart of water or 1½ teaspoonsful of solution for each pint of water [bullet] add solution directly to cold water only in a hot steam vaporizer [bullet] follow manufacturer's directions for using vaporizer or *For products formulated to be placed in the medication chamber of a hot steam vaporizer.* [bullet] place water in the vaporizer and follow manufacturer's directions for using vaporizer [bullet] place solution in the medication chamber only) [bullet] breathe in the medicated vapors [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(v) *For products containing menthol identified in § 341.14(b)(2) for steam inhalation use.* The product contains 3.2 percent menthol. "[bullet] see important warnings under 'When using this product'"[appears as the first statement under the heading "Directions" and is highlighted in bold type] [bullet] adults and children 2 years and older: (select one of the following, as appropriate: *For products formulated to be added directly to cold water inside a hot steam vaporizer.* [bullet] use 1 tablespoonful of solution for each quart of water or 1\1/2\ teaspoonsful of solution for each pint of water [bullet] add solution directly to cold water only in a hot steam vaporizer [bullet] follow manufacturer's directions for using vaporizer or *For products formulated to be placed in the medication chamber of a hot steam vaporizer.* [bullet] place water in the vaporizer and follow manufacturer's directions for using vaporizer [bullet] place solution in the medication chamber only) [bullet] breathe in the medicated vapors [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

(f) *Exemption from the general accidental overdose warning.* The labeling for antitussive drug products containing the active ingredient identified in § 341.14(b)(2) marketed in accordance with § 341.74(d)(2)(iii) is exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

[52 FR 30055, Aug. 12, 1987; 52 FR 35610, Sept. 22, 1987; 53 FR 35809, Sept. 15, 1988; 55 FR 27808, July 6, 1990; 55 FR 40383, Oct. 3, 1990; 58 FR 54236, Oct. 20, 1993; 59 FR 29174, June 3, 1994; 59 FR 36051, July 15, 1994; 64 FR 13295, Mar. 17, 1999; 65 FR 8, Jan. 3, 2000; 65 FR 46867, Aug. 1, 2000; 67 FR 72559, Dec. 6, 2002]

§ 341.76 Labeling of bronchodilator drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "bronchodilator."

Maryland Medical Center Programs

Complementary Medicine Program

Table of Contents > Conditions > Bronchitis Print

Bronchitis

Also Listed As: Respiratory Infection, Bronchitis

Bronchitis is a respiratory tract infection (viral or bacterial) that causes inflammation of the mucous lining of the bronchial tubes. Acute bronchitis generally is reversible. Chronic bronchitis, often referred to as smoker's cough, is not usually reversible.

Top

Signs and Symptoms

Acute bronchitis:

- Cough that produces mucus or pus
- Burning sensation in the chest
- Sore throat and fever (with some types)
- Fatigue
- Blue-tinted lips
- Wheezing
- Weight gain

Chronic bronchitis:

- Chronic cough that produces excessive amounts of mucus or pus
- Wheezing, shortness of breath
- Present for three consecutive months, two years in a row

Top

What Causes It?

Acute bronchitis is usually caused by a virus, but can also be caused by bacteria. Generally, acute bronchitis is passed

RELATED INFORMATIO

Conditions with Simila Symptoms

- View Conditions

Drugs

- Antibiotics
- Bronchodilators
- Corticosteriod Medication
- Expectorants

Herbs

- Eucalyptus
- Garlic
- Ginger
- Licorice
- Linden
- Lobelia

Supplements

- Cysteine
- Vitamin C (Ascorbic Acid)

Learn More About

- Acupuncture
- Herbal Medicine
- Homeopathy
- Massage
- Nutrition

from person to person. The main causes of chronic bronchitis are cigarette smoking and prolonged exposure to air pollution or other irritants such as dust and grain.

Top

Risk Factors

- Cigarette smoking
- Severe pneumonia early in life
- Being a man over age 50

Top

What to Expect at Your Provider's Office

Your provider will listen to your chest and back, look at your throat, and may draw blood and take a culture of the secretions from your lungs.

Top

Treatment Options

Treatment Plan

Chronic bronchitis may be irreversible but it is preventable. The best way to avoid bronchial infections is to not smoke and to stay away from air pollutants. Your health care provider may prescribe antibiotics to help treat your bronchitis if it is caused by bacteria. He or she may also suggest using a humidifier, taking a cough medicine that contains an expectorant (something that helps you "bring up" secretions), and drinking plenty of fluids.

Top

Drug Therapies

- Bronchodilators (such as albuterol)
- Corticosteroids (20 to 40 mg per day of prednisone or 100 to 200 mcg, 2 to 4 puffs per day of inhaled beclomethasone) to reduce mucus and inflammation
- Cough suppressants
- Expectorant medication (10 to 12 drops 3 times daily of potassium iodide) or tracheal suction
- Antibiotics for bacterial infection (250 to 500 mg of penicillin or tetracycline every 6 hours for 10 days)
- Oxygen for hypoxia (a lower-than-normal concentration of oxygen in the blood): more than 12 hours per day required to be effective

Top

Complementary and Alternative Therapies

Alternative therapies can be useful in treating chronic bronchitis.

Top

Nutrition

- Eliminate known allergenic foods (for example, eggs, milk, nuts, peanuts, soy), food coloring, preservatives, and additives. Reduce intake of mucus-producing foods such as dairy, citrus, wheat, and bananas. Onions and garlic help to thin mucus.
- Vitamin C (250 to 500 mg two times per day), zinc (30 mg per day), and beta-carotene (50,000 to 100,000 IU per day) support the immune system. Some studies suggest that smokers do not use beta-carotene. N-acetylcysteine (200 mg twice a day between meals) protects lung tissue from damage and helps break up mucus.

Top

Herbs

Herbs may be used as dried extracts (capsules, powders, teas), glycerites (glycerine extracts), or tinctures (alcohol extracts). Herbs can be used in combination. Tincture combinations should be taken at 30 drops three to four times per day. Make infusions with 1 heaping tsp. of herbal combination, steep covered for 10 minutes, and drink 3 to 4 cups per day. Substitute grindelia *(Grindelia robusta) for* licorice root if you have high blood pressure.

- Acute bronchitis: Thyme leaf *(Thymus vulgaris),* licorice root *(Glycyrrhiza glabra),* coneflower *(Echinacea purpurea),* ginger *(Zingiber officinale),* and linden flowers *(Tilia cordata).* Smokers should substitute Indian tobacco *(Lobelia inflata)* for the linden flowers. White horehound *(Marrubium vulgare)* is a gentle stimulating expectorant (helps you cough up mucus) that relaxes spasms of the bronchi (passages in the lungs). Sundew *(Drosera rotundifolia)* helps you cough up mucus and relaxes spasms.
- Chronic bronchitis: Pleurisy root *(Asclepias tuberosa),* Indian tobacco *(Lobelia inflata),* elecampane *(Inula helenium),* licorice root, lungwort *(Sticta pulmonaria),* and lomatium *(Lomatium dissectum).* Boneset *(Eupatorium perfoliatum),* is an herb that helps to sweat out impurities and relax spasms. Pill bearing spurge *(Euphorbia hirta)* is an herb that breaks up mucus and relaxes spasms.
- Garlic *(Allium sativum)* and ginger tea can be used long-term (2 cloves of garlic and 2 to 3 slices of ginger root). Simmer in 1 cup of water for 15 minutes. Drink 3 to 4 cups per day. Add honey or lemon to flavor.

Homeopathy

Although very few studies have examined the effectiveness of specific homeopathic therapies, professional homeopaths may consider the following remedies for the treatment of bronchitis in addition to standard medical care. Before prescribing a remedy, homeopaths take into account a person's constitutional type. A constitutional type is defined as a person's physical, emotional, and psychological makeup. An experienced homeopath assesses all of these factors when determining the most appropriate treatment for each individual.

- *Aconitum* -- for early stages of respiratory disorders such as bronchitis; this remedy is most appropriate for people with a hoarse, dry cough who complain of dry mouth, thirst, restlessness, and being awakened by coughing; symptoms tend to worsen in cold air or when when lying on one's side
- *Antimonium tartaricum* -- for wet, rattling cough (although the cough is usually too weak to bring up mucus material from the lungs) that is accompanied by extreme fatigue and difficulty breathing; symptoms usually worsen when the person is lying on his or her back; this remedy is particularly good for children and the elderly and is generally used during the later stages of bronchitis
- *Bryonia* -- for dry, painful cough that tends to worsen with movement and deep inhalation; this remedy is most appropriate for individuals who are generally thirsty, chilly, and irritable
- *Hepar sulphuricum* -- for later stages of bronchitis, accompanied by wheezing, scant mucus production, and coughing that occurs when any part of the body gets cold
- *Ipecacuanha* -- for the earliest stages of bronchitis accompanied by a deep, wet cough, nausea and vomiting; this remedy is commonly prescribed for infants
- *Phosphorus* -- for several different types of cough but usually a dry, harsh cough accompanied by a persistent tickle in the chest and significant chest pain; this remedy is most appropriate for individuals who are often worn out and exhausted, tend to be anxious and fear death, and require a lot of reassurance

Top

Physical Medicine

- Castor oil pack. Apply oil directly to skin, cover with a clean soft cloth and plastic wrap. Place a heat source (hot water bottle or heating pad) over the pack and let sit for 30 to 60 minutes.
- Chest rubs with 3 to 6 drops of essential oil in 1 tbsp. of food-grade oil. Thyme, eucalyptus, and pine oils can ease bronchial spasm and thin mucus.
- Running a humidifier with essential oils such as eucalyptus, tea tree, or marjoram at night may help thin mucus and ease cough.
- Postural drainage can be of great help in relieving congestion.

Top

Acupuncture

Acupuncturists treat people with bronchitis based on an individualized assessment of the excesses and deficiencies of qi located in various meridians. Needling treatment for bronchitis tends to focus on the lung and spleen meridians. Acupuncturists usually perform other treatments as well to clear the blockage of qi in the chest area. These treatments may include specialized massage, moxibustion (a technique in which the herb mugwort is burned over specific acupuncture points), breathing exercises, lifestyle counseling, and herbal remedies.

Top

Massage

Therapeutic massage can increase circulation and loosen mucus.

Top

Following Up

It can take from one to eight weeks to recover completely. To help prevent getting bronchitis again, do not smoke and try to avoid pollutants in the air. Getting an annual flu shot can also help.

Top

Supporting Research

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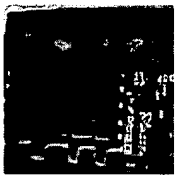

Illnesses & Conditions

Information on diseases and health concerns, including sym treatment options, and prevention.

Coughs

healthw for every health

Topic Overview

Coughing is the body's way of removing foreign material or mucus from the lungs and upper airway passages or of reacting to an irritated airway. Coughs have distinctive traits you can learn to recognize. A cough is only a symptom, not a disease, and often the importance of your cough can be determined only when other symptoms are evaluated.

Productive coughs

A productive cough produces phlegm or mucus (sputum). The mucus may have drained down the back of the throat from the nose or sinuses (postnasal drainage) or may have come up from the lungs. A productive cough generally should not be suppressed; it clears mucus from the lungs. There are many causes of a productive cough, such as:

- Viral illnesses. It is normal to have a productive cough when you have a common cold. Coughing is often triggered by mucus that drains down the back of the throat.
- Infections. An infection of the lungs or upper airway passages can cause a cough. A productive cough may be a symptom of pneumonia, bronchitis, sinusitis, or tuberculosis.
- Chronic lung disease. A productive cough could be a sign that a disease such as chronic obstructive pulmonary disease (COPD) is getting worse.
- Stomach acid backing up into the esophagus. This type of coughing may be a symptom of gastroesophageal reflux disease (GERD) and may awaken you from sleep.
- Nasal discharge draining down the back of the throat (postnasal drip syndrome). This can cause a productive cough or the feeling that

you constantly need to clear your throat. Experts disagree about whether a postnasal drip or the viral illness that caused it is responsible for the cough.
- Smoking or other tobacco use. Productive coughs in a person who smokes or uses other forms of tobacco is often a sign of lung damage or irritation of the throat or esophagus..

Nonproductive coughs

A nonproductive cough is dry and does not produce sputum. A dry, hacking cough may develop toward the end of a cold or after exposure to an irritant, such as dust or smoke. There are many causes of a nonproductive cough, such as:

- Viral illnesses.
  - After a common cold, a dry cough may last several weeks longer than other symptoms and often gets worse at night.
  - Severe acute respiratory syndrome (SARS) is a newly identified respiratory illness that infected people in parts of Asia, North America, and Europe in early 2003. The main symptoms of SARS are a fever higher than 100.4 °F(38 °C), a dry cough, shortness of breath, and difficulty breathing.
- Bronchospasm. A nonproductive cough, particularly at night, may indicate spasms in the bronchial tubes (bronchospasm) caused by irritation.
- Allergies. Frequent sneezing is also a common symptom of allergic rhinitis.
- Medications called ACE inhibitors that are used to control high blood pressure. Examples of ACE inhibitors include captopril (Capoten), enalapril maleate (Vasotec), and lisinopril (Prinivil, Zestril, or Zestoretic).
- Exposure to dust, fumes, and chemicals in the work environment.
- Asthma. A chronic dry cough may be a sign of mild asthma. Other symptoms may include wheezing, shortness of breath, or a feeling of tightness in the chest. For more information, see the topic Asthma.

Coughs in children

Children may develop coughs from diseases or causes that usually do not affect adults, such as:

- Croup.
- Bronchiolitis.
- Infection of the lower respiratory system (such as caused by respiratory syncytial virus, or RSV).
- A foreign object, such as a toy or a food item, stuck in the airway.
- Exposure to secondhand smoke from parents or caregivers who smoke.
- Emotional or psychological problems. A dry, nonproductive "psychogenic cough" is seen more frequently in children than in adults.

Many coughs are caused by a viral illness. Antibiotics are not used to treat viral illnesses and do not alter the course of viral infections. Unnecessary use of an antibiotic exposes you to the risks of an allergic reaction and antibiotic side effects, such as nausea, vomiting, diarrhea, rashes, and yeast infections. Antibiotics also may kill beneficial bacteria and encourage the development of dangerous antibiotic-resistant bacteria.

A careful evaluation of your health may help you identify other symptoms. Remember, a cough is only a symptom, not a disease, and often the importance of your cough can only be determined when other symptoms are evaluated. Coughs occur with bacterial and viral respiratory infections. If you have other symptoms, such as a sore throat, sinus pressure, or ear pain, see the Related Information section.

Review the Emergencies and Check Your Symptoms sections to determine if and when you need to see a health professional.

Author: Sydney Youngerman-Cole, RN, BSN, RNC
Last Updated April 26, 2004

Medical Review: William M. Green, MD - Emergency Medicine
Donald Sproule, MDCM, CCFP - Family Medicine

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ST. VINCENT CARMEL HOSPITAL

health connections

A Quarterly Publication

Fall 2003

Eight simple steps to staying out of the ER

In April 2003, St.Vincent Carmel opened its expanded Emergency Department so it could continue to provide excellent care in a more efficient manner to patients who require emergency treatment. But efficient designs and processes aside, the fastest way to get out of the emergency room is to not have to go there at all!

James L. Nevin, Jr., M.D. is a St.Vincent emergency medicine physician who believes that a little common sense and planning can help you avoid many situations that might send you to the emergency room.

Dr. Nevin's rules for avoiding the emergency room:

1. Prevention is key. Protecting yourself from injuries can be as simple as taking a few preventative measures before you begin a task. Wearing eye guards or sunglasses can protect you from eye injuries that may come from rocks and debris thrown by weed whackers and powerful lawn blowers. Dressing for the weather – layering your clothing and wearing a hat for sun protection and heat conservation, is a simple way to prevent overheating and cold-exposure injuries. If hanging lights or other decorations, be certain your ladder is in good condition and on stable ground. Have someone help by steadying the ladder while you're on it.

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What's Inside...

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2. Familiarity breeds good health. "Be familiar with your surroundings," said Dr. Nevin. "Know where you are going." A quick check of a map when driving to a location you're unfamiliar with can give you a better sense of where you're going and what you'll encounter along the way. That simple step gives you confidence about your destination and allows you to better concentrate on the road ahead. If a nice hike through the woods is on your list of favorite fall activities, be familiar with the plants and animals you may come in contact with. Know what poison ivy looks like. Know how to recognize a tick. Taking the time to become familiar with your surroundings can help ensure you won't need to become familiar with the emergency room!

3. Stop and think – especially when using power tools. It sounds easy enough but Dr. Nevin has seen plenty of patients who didn't stop and think. Power tools can make work so easy and effortless; it's easy to lose concentration. "The consequences are unbelievable," said Dr. Nevin. "Pay attention. Don't put your hands in places you can't see." Each year, many people lose fingers when they reach into a machine to dislodge snow, grass or leaves. First, turn the machine off or wait for the blades to stop spinning, even after the power is off.

4. Use caution in a car. The easiest way to prevent injuries when traveling in a car is to buckle up. But there are other things you can do to prevent injuries while driving or riding in a car. Don't eat or drink in the car. Hot food and drinks can cause burns if spilled on your lap, and food and drink can also be distracting. Trying to drive while eating a cheeseburger and reaching for a drink is unsafe. Keeping your hands at 10 and 2 on the wheel is safer. Cell phones also provide unnecessary distractions. If you must talk and drive, invest in a speaker phone system for the car.

5. Respect animals. Puppies and kittens may seem cute and cuddly, but don't get too cozy with an animal unfamiliar to you. "Dogs are territorial," said Dr. Nevin. "Avoid invading their territory whenever possible." Dr. Nevin advises using special caution when children and animals are in the same space. "Always put yourself between the child and the dog when going for a walk," Dr. Nevin cautions. This can keep a dog from snapping at a child who walks too closely. Caution should also be used with cats. Cat scratches and bites have sent plenty of people seeking medical treatment. And of course, stay away from wild animals. If you happen upon an animal in the woods, respect the fact that you are in its home. Do not attempt to pet or catch any animal you find in the wild.

6. Wash your hands. The simple act of washing your hands is the best way to protect yourself from germs you may catch while shaking hands, working in the yard or receiving a cut or scratch. "The solution to pollution is dilution," Dr. Nevin said. This catchy saying is an easy way to remember that even rinsing well with plain tap water can wash away germs.

7. Enjoy your alcohol wisely. Fall brings with it tailgate parties and Sunday afternoons of football on TV, both of which usually involve alcohol. So do holiday parties. If you like to include alcohol in your social activities, do so wisely to avoid impaired judgement. "Increased alcohol consumption increases the risk for weather exposure, accidents with tools and falls, to name a few," said Dr. Nevin. And never get behind the wheel if you've been drinking.

8. Put stress to rest. According to Dr. Nevin, stress is an underlying factor in many of the injuries seen in the emergency room. "Stress can have a domino effect," Dr. Nevin said. "It makes you unfocused, hurried, can lead you to drink more and can contribute to depression and anxiety." Combat stress by taking time to slow down each day. Engage in relaxing activities or simply rest. If your stress is so great that you can't get a handle on it yourself, talk to your doctor.

The Emergency Department at St. Vincent Carmel Hospital handles over 16,000 emergency visits a year. Follow these safety rules so you don't become part of this statistic. To learn more and receive a free first aid slide guide, **call 338-CARE.**

Core Value Winners

Fourth Quarter Core Value Award Winners Announced

The Core Value Awards recognize associates and volunteers who exemplify our Core Values. Associates and volunteers are nominated by fellow staff, and one individual is selected for each of the six values: Service of the Poor, Reverence, Integrity, Wisdom, Creativity and Dedication.

Congratulations to the following winners:

Michelle Slayman
Integrity

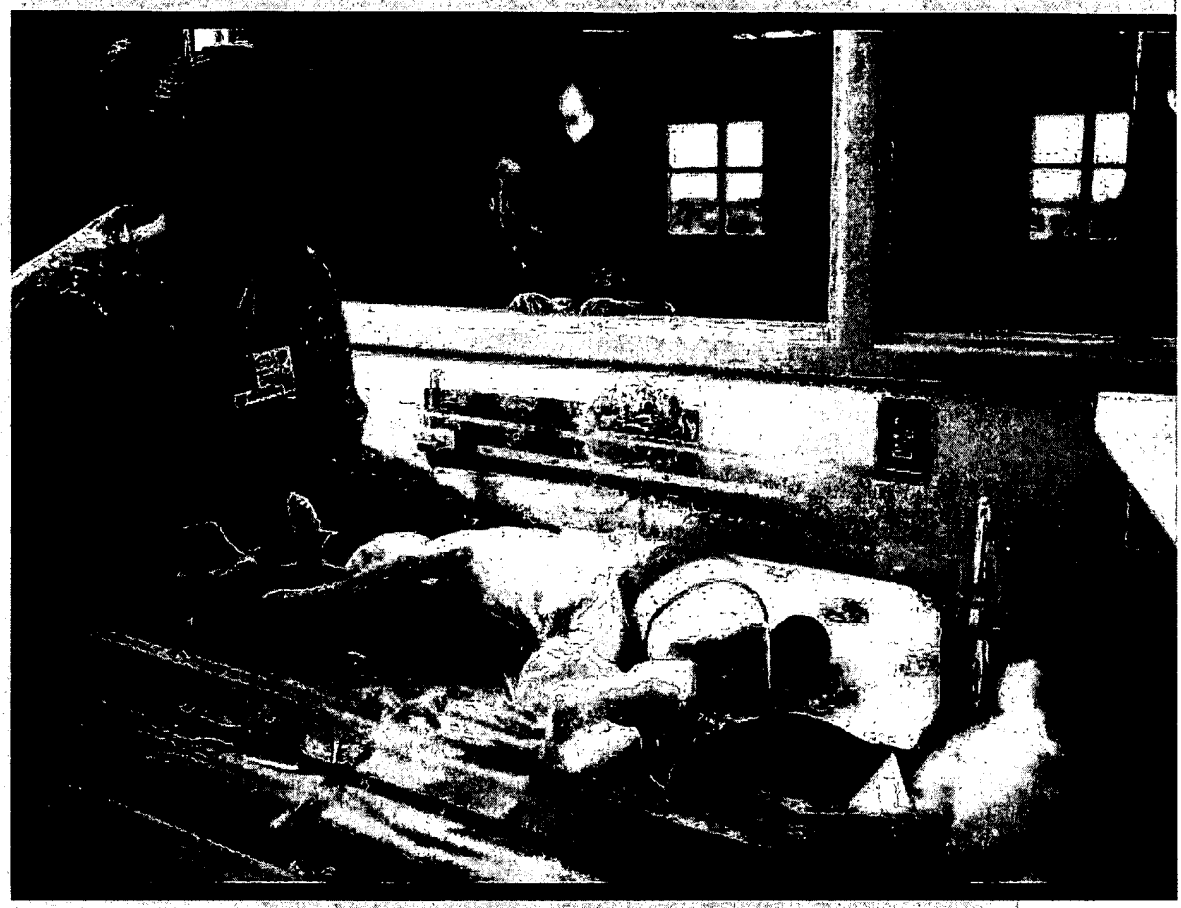
Becky Hodson
Creativity

Terry Stutesman
Reverence

Phil Bowles
Dedication

Robert Bichel
Service of the Poor

Jacquelyn Toomey
Wisdom



Knowing your baby is essential for healthy, newborn care

It's the stuff that can keep new mothers – and fathers – awake at night, long after baby has drifted off to sleep.

"Is she getting enough to eat?"

"Oh, his first cold. It is just a cold, isn't it?"

Newborns can be amazing, wonderful and perplexing — all at the same time. In a society that seems to be high-tech everything, caring for a newborn would be an easier task if they came with fuel gauges and "check engine" lights. The cues your baby gives may be more subtle — or not so subtle if your baby is the screaming sort! But the cues are there, said Thomas Boyce, M.D., a pediatrician at Hazel Dell Pediatrics.

How much worry is enough?

Many parents worry whether their baby is getting enough nutrition, especially if the baby is breastfed, since there is no easy way to measure how many ounces of breastmilk baby is consuming on a daily basis.

Boyce encourages parents to use urine output and weight gain as a guide in determining adequate nutrition.

"A baby should be making four to six wet diapers a day in the first few days of life and then six to eight wet diapers a day after the first week," Boyce said. "Most infants will lose some weight after they are born, but we look for a baby to be back to his or her birth weight at about seven to ten days old."

Parents should keep in mind that newborns will eat frequently, every one to four hours for breastfed infants; every two to four hours for formula-fed babies.

"If you're lucky enough to have a baby who sleeps four to five hours, it's ok to let them sleep," said Boyce. "But newborns should not go any longer than four to five hours without eating."

So, even though conventional wisdom may say "never wake a sleeping baby," if your baby has been sleeping for more than four hours, it's time to wake him/her for a feeding.

Is baby really hungry?

Some babies have a strong need to suck. So how do you know if your baby, who is sucking on his or her hand, is really hungry or just sucking for the calming effect?

Boyce said babies who need to suck to soothe themselves will do so in a sleepy state and often they've recently been fed. According to Boyce, if your baby is sucking on his hand and it has been more than one to two hours since the last

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Make this your year to beat the flu

Jessica Saberman, M.D., is a family practice physician, certified by the American Board of Family Physicians, a member of the American Academy of Family Physicians, and an advocate for influenza knowledge and prevention. From her offices at Fishers Primary Care, at 115th and Allisonville in Fishers, she answered our questions about the upcoming flu season.

What is influenza (the flu)?

Saberman: Influenza is a respiratory virus that infects the nose, throat and lungs. Unlike many other viral respiratory infections, such as the common cold, the flu may cause severe illness and life-threatening complications in certain people.

What are the symptoms of the flu?

Saberman: I like to help patients distinguish between ailments that are commonly called the flu, and those that are true influenza. In everyday conversation, many people refer to any condition exhibiting a runny nose, cough and muscle aches as "the flu." More often than not, these ailments are not true influenza and can be caused by a number of different, and less severe, viral illnesses.

The actual flu is caused by a particular virus called Influenza, types A or B. You know when you have the flu, because you feel like you've been hit by a truck. Patients who have influenza, rather than the typical head cold, will suffer with high fever, extreme malaise or fatigue, headaches, muscle and body aches, and often a sore throat and runny or stuffy nose. Also, the flu usually produces a dry cough, rather than the loose or wet cough associated with a cold.

Children with influenza can have additional gastro-intestinal symptoms, such as nausea, vomiting, and diarrhea, but these symptoms are uncommon in adults.

"Think of it this way: you may not suffer acutely if you get the flu this year, but you could easily spread it to others who are less healthy and susceptible to complications. The more healthy people who receive flu shots, the lower the overall incidence of flu will be."

Dr. Jessica Saberman, family physician

Is there anyone who should not receive a flu shot?

Saberman: People who are allergic to eggs should not have the shot, as the vaccine contains egg proteins. And, if a person has had a truly severe reaction to the flu shot in the past — so severe that they were forced to see a doctor — they have probably been warned by their doctor not to get another one.

The flu will almost always put you out of commission for a good couple of days.

Are colds caused by viruses, too?

Saberman: Yes. Most URIs (Upper Respiratory Infections) are actually viral infections, though it's hard to know what's viral and what's bacterial. I remind people that the color of your phlegm does not tell me whether you have a virus or a bacterial infection; viruses can also cause colorful drainage.

While influenza comes on suddenly, a cold has a more gradual onset. A cold's typical progression can last two weeks, starting with a sore throat and moving toward the chest, with a lingering cough lasting another two weeks.

Is there really such a thing as a "Stomach Flu"?

Saberman: That is another misnomer. Although the term "stomach flu" is sometimes used to describe vomiting, nausea, or diarrhea, these illnesses are caused by certain other viruses, bacteria, or possibly parasites, and are rarely related to influenza.

How many people get sick or die from the flu every year?

Saberman: The CDC (Center for Disease Control) says that each year, about 10 percent to 20 percent of U.S. residents get the flu, and an average of 114,000 persons are hospitalized for flu-related complications, like pneumonia, dehydration, and worsening of chronic medical conditions. About 36,000 Americans die each year from the complications of flu.

How do I know if I have the flu?

Saberman: See a doctor, especially if you have a high fever, a dry cough and severe symptoms. It is very difficult to distinguish the flu from other URIs on the basis of symptoms alone. We do have a test that can confirm influenza.

How soon will I get sick if I am exposed?

Saberman: The time from when a person is exposed to flu virus to when symptoms begin is about one to four days, with an average of about two days.

How long is a person with flu virus contagious?

Saberman: Adults may be contagious from one day prior to becoming sick and for three to seven days after they first develop symptoms. Some children may be contagious for longer than a week.

We don't want you to get it. Here's what to know if you do.

What can I do to protect myself against the flu?

Saberman: Prevention is absolutely the best way to overcome the flu – and the best way to prevent it is to get a yearly flu shot! During flu season, try to avoid situations where the virus is likely to be spread. Everyone in your family wash their hands, avoid sharing utensils and cups, and cover the nose and mouth when sneezing or coughing.

How is influenza treated?

Saberman: We recommend acetaminophen, fluids, and bed rest. A flu patient should feel better by day five. Parents should never give aspirin to children or teenagers suffering from influenza, as they could develop a rare but severe condition called Reye Syndrome. Also, we have a few anti-viral medications that will not cure influenza, but will reduce its severity and duration, if administered during the first two days.

Are there any new developments in influenza prevention and treatment?

Saberman: A new flu prevention treatment, in the form of a nasal spray, has recently been approved by the FDA for low-risk persons. However, I do not recommend the spray, as it may not be as safe or effective, and it remains unproven among the general population. Also, it is much more expensive than the shot.

Get a flu shot. It's safe and it's worth it.

By far, the single best way to prevent the flu is for individuals, especially those with high risk or high exposure, to get a flu shot each fall. Here's what Dr. Saberman says:

Who should get a flu shot?

Saberman: First and foremost, anyone who is at high risk for developing serious complications. I strongly recommend that anyone over 65, and between the ages of six months and two years, go ahead and get the shot. Also, persons of any age who suffer from a chronic lung or heart condition, HIV, diabetes or any chronic disorder, should have flu shots.

"If you see someone close to you suffer with influenza you'll know you don't want it."
Jessica Saberman, M.D.

Not just professional health care and public service providers, but home caregivers, mothers of young children, teachers and day care workers should have flu shots. The flu shot is recommended for cancer patients who are undergoing chemotherapy. And people who are under a great deal of stress, for any reason, are wise to have a flu shot.

These recommendations come from the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatricians.

OB-GYNs (obstetrician-gynecologists) recommend the flu shot for women who are pregnant or will become pregnant through the flu season. You don't want to get that sick while pregnant and, for instance, not be able to eat. The flu shot is safe for breast feeding women.

Beyond that, I personally advocate flu shots for everyone who can have them.

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Flu fact versus flu fiction: disarming the myths.

There are several common myths about flu, including:

Myth #1: Influenza is merely a nuisance.
Wrong. Influenza is a major cause of illness and death in the United States and leads to an average of about 36,000 deaths and 114,000 hospitalizations per year.

Myth #2: Flu shots cause the flu.
Wrong. The licensed injectable flu vaccine used in the United States, which is made from inactivated or killed flu viruses, cannot cause the flu and does not cause flu illness.

Myth #3: Flu vaccine doesn't work.
Not exactly. When the viruses in the vaccine and circulating viruses are similar, the flu shot is very effective. There are several reasons why people think influenza vaccine doesn't work. People who have gotten a flu vaccination may then get sick from a different virus that causes respiratory illness but is mistaken for flu; the flu shot only prevents illness caused by the influenza virus. Also, there are a few cases each year in which the vaccine has not been 100 percent effective.

Myth #4: There is no need to get a flu vaccine every year.
Wrong. The flu viruses are constantly changing. Generally, new influenza virus strains circulate every flu season, so the vaccine is changed each year.

Source: United States Department of Health and Human Services, Centers for Disease Control and Prevention. www.CDC.gov.

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Flu season: Ready or not...

When is the flu season in the United States?

Saberman: We see most cases of the flu from October through May. Flu season peaks anywhere from late December through March. We vaccinate from October through November, though we will do it as late as December. It takes about two weeks after the shot to develop full immunity.

The CDC (Center for Disease Control) does a great job of tracking influenza during winter months. Their reports are on the Internet at www.cdc.gov.

How might this flu season be different from the last?

Saberman: I don't think it's going to be different. However, an interesting news topic will be SARS and influenza. If SARS picks up in the world again it might become difficult to differentiate influenza from SARS. Last season everyone with a cough and cold was wondering if they had SARS. That's another advantage for people who have the flu shot. If they do show severe respiratory symptoms, we'd be able to rule out influenza as a cause.

"I always get the flu shot. I know it might hurt my arm for a good day, but I do it because I believe that it definitely makes a difference."

Dr. Jessica Saberman

Where can a person get a flu shot?

Many pharmacies, employers and other organizations offer free or low-cost flu shots during the fall. Area seniors can obtain the influenza vaccination and counseling at the upcoming Senior Health Fair to benefit PrimeLife Enrichment (formerly Hamilton County Senior Services.) The fair is Friday, October 24, 2003, from 8 a.m. to Noon at PrimeLife Enrichment located at 1078 Third Avenue SW in Carmel. Seniors can visit the fair for their flu shot and receive free health information and screenings from local vendors.

To learn more, talk to your primary health-care provider or log onto the CDC at www.cdc.gov. Also, St.Vincent Immediate Care on Hazel Dell will be offering flu shots for $20 beginning mid-October.

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feeding, he/she may be hungry again. Try offering the breast or bottle. Vigorous sucking from a crying baby is a telltale sign of hunger.

According to Boyce, if a breastfed baby has nursed 10 to 15 minutes on each breast and is still sucking sleepily, it's ok to remove baby from the breast.

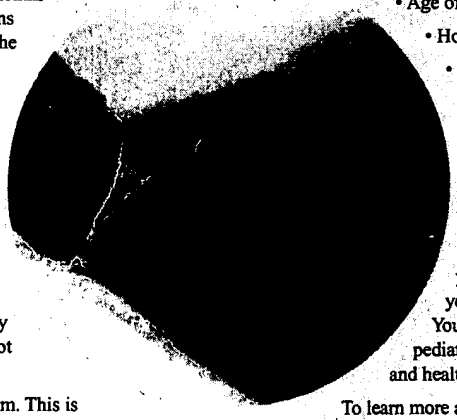
When should I call the doctor?

If you suspect that your baby is not eating enough, Boyce believes a call to the pediatrician is in order.

"We are especially cautious with kids under 3 months old," Boyce said. "A parent who has any concerns about his or her child shouldn't hesitate to call the pediatrician."

Boyce said contact with the pediatrician is especially important in the following instances:

- Baby is making less than the number of wet diapers your doctor told you to look for.
- Baby has a rectal temperature of 100.5 degrees or higher.
- Baby is lethargic. While newborns typically sleep a lot, a baby who is lethargic will be truly difficult to wake, will not feed well and will not have awake and alert periods during the day.
- Baby's skin and eyes have a yellow tint to them. This is called jaundice. Boyce said any yellowing below the nipple line is cause for a call to the pediatrician.
- Baby has inconsolable crying.
- Baby is blue around the mouth, lips and tongue, especially when feeding. A bluish cast to your baby's palms and soles of the feet is normal.



What information should I have on hand?

If you have any concerns about your baby's health and development, your call to the pediatrician will be more productive if you have certain information on hand to give to the nurse or receptionist who takes your call.

Boyce suggests having the following information available:

- Age of your baby (in weeks is ok)
- How well your baby has been eating that day
- Diaper output
- Baby's temperature
- List of any complications from delivery

All this information helps the pediatrician's staff determine if your baby needs to be seen in the office.

Even if you are a brand new parent, you know your baby best. Learn your baby's cues and trust your instincts when it comes to his or her health. You don't, however, have to go at it alone. Use your pediatrician as an important ally in raising a happy and healthy child.

To learn more about St.Vincent physicians and Carmel's new maternity service, simply call the CareLine at 338-CARE.

Community Outreach

Colon Cancer Screening

November 6, 2003

At St.Vincent Carmel Hospital

Appointments are from 6:00 p.m. until 7:30 p.m.

Entrance #1 – Main Lobby

Men and women age 40 and above are eligible. Under 40 if there is a family history of colon cancer.

Screening takes about 15 minutes per participant.

A hemoccult kit is mailed to your home. You bring the completed kit with you on the day of the screening and it is developed by a nurse. A physician is available for consultation.

All community cancer screenings are free to the public.

To schedule an appointment, call the St.Vincent CARELine at 338-CARE (2273).

Senior Lecture

November 13, 2003

2:00 p.m. to 4 p.m.

Do Steak & Corn-on-the-Cob Still Make You Smile?

If not, come and find out some ways advanced dentistry can help you compensate for tooth loss and bite problems. It can also help you improve the appearance of teeth that are no longer attractive. Christine Bishop, D.D.S, dentist, will serve as host of the lecture.

Refreshments and free blood pressure checks are also available.

No registration fee.

St.Vincent Carmel Hospital, Professional Building, Room 255, Entrance #3, elevator C, to the second floor.

Senior Health Fair

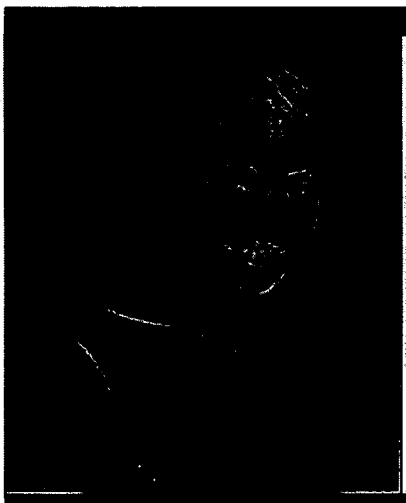
Friday, October 24, 2003

8:00 a.m. to Noon

Free to area seniors. Vendors and screenings, including hearing screens, health risk appraisals, flu shots and more.

Held at PrimeLife Enrichment Center, 1078 Third Ave SW, Carmel, IN 46032

Call (317) 815-7000 for details.



St.Vincent Carmel Partners with Westfield High School

Alison Norris is a senior at Westfield High School and is participating in the school mentoring program. Alison was thrilled to know St.Vincent Carmel Hospital was a sponsoring site for the program because she wants to be an OB nurse.

Alison plans to attend Indiana University, Bloomington. She has two sisters, a brother, two dogs and two cats. She is the daughter of Steve and Shari Norris of Westfield.

THE MERCK INDEX

AN ENCYCLOPEDIA OF
CHEMICALS, DRUGS, AND BIOLOGICALS

TWELFTH EDITION

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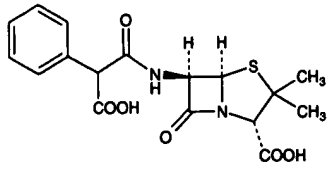
1233; Gritz, Naumann, *ibid.* 1237. Toxicity data: E. I. Goldenthal, *Toxicol. Appl. Pharmacol.* **18,** 185 (1971).

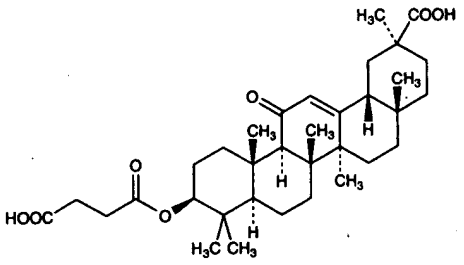


Disodium salt, $C_{17}H_{16}N_2Na_2O_6S$, ***carbenicillin disodium, BRL-2064, CP-15639-2, Anabactyl, Carbapen, Carbecin, Geopen, Hyoper, Microcillin, Pyocianil, Pyopen.*** White powder. LD_{50} i.p. in rats: > 2000 mg/kg (Goldenthal).

Phenyl sodium, $C_{23}H_{21}N_2NaO_6S$, ***carfecillin sodium, BRL-3475, Gripenin-O, Urocarf, Uticillin.*** Prepn and activity studies: Clayton *et al., J. Med. Chem.* **18,** 172 (1975). Crystals from ethanol, $[\alpha]_D^{20}$ +216.2° (H_2O).

THERAP CAT: Antibacterial.

1839. Carbenoxolone. ***(3β,20β)-3-(3-Carboxy-1-oxopropoxy)-11-oxoolean-12-en-29-oic acid; 3β-hydroxy-11-oxoolean-12-en-30-oic acid hydrogen succinate;*** 3-*O*-(β-carboxypropionyl)-11-oxo-18β-olean-12-en-30-oic acid; 18β-glycyrrhetic acid hydrogen succinate; carbenoxalone. $C_{34}H_{50}O_7$; mol wt 570.77. C 71.55%, H 8.83%, O 19.62%. Anti-inflammatory glucocorticoid related to enoxolone, *q.v.* Prepn: Gottfried, Baxendale, **Brit.** pat. **843,133; U.S.** pat. **3,070,623** (1960, 1961 to Biorex). Monograph: *Carbenoxolone Sodium,* J. M. Robson, F. M. Sullivan, Eds. (Butterworths, London, 1969) 263 pp. Symposium on clinical efficacy: *Scand. J. Gastroenterol.* **15,** Suppl. 65, 1-121 (1980). Effect on gastric prostaglandin levels in humans: J. Rask-Madsen *et al., Eur. J. Clin. Invest.* **13,** 351 (1983); P. Minuz *et al., Pharmacol. Res. Commun.* **16,** 875 (1984).

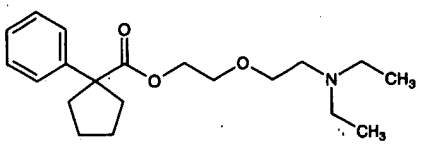


Cream-colored crystals, mp 291-294°. $[\alpha]_D^{20}$ +128° (chloroform).

Disodium salt, $C_{34}H_{48}Na_2O_7$, ***Biogastrone, Bioplex, Bioral, Duogastrone, Neogel, Pyrogastrone, Sanodin, Ulcus-Tablinen.*** Creamy-white solid. Freely sol in water. LD_{50} in male mice (mg/kg): 198 i.v.; 120 i.p.; in male rats (mg/kg): 3200 orally (Robson, Sullivan).

THERAP CAT: Antiulcerative.

1840. Carbetapentane. ***1-Phenylcyclopentanecarboxylic acid 2-(2-diethylaminoethoxy)ethyl ester;*** 2-(diethylaminoethoxy)ethyl 1-phenyl-1-cyclopentanecarboxylate; 2-(diethylaminoethoxy)ethyl 1-phenylcyclopentyl-1-carboxylate; 1-phenylcyclopentane-1-carboxylic acid diethylaminoethoxyethyl ester; pentoxyverine; pentoxiverin; Atussil. $C_{20}H_{31}NO_3$; mol wt 333.47. C 72.04%, H 9.37%, N 4.20%, O 14.39%. Prepn: H. G. Morren, **Brit.** pat. **753,779;** *idem,* **U.S.** pat. **2,842,585** (1956, 1958 both to Union Chimique Belge). Antispasmodic activity: D. Wellens, *Arzneimittel-Forsch.* **17,** 495 (1967). Clinical effect on lung function: E. Krieger, *ibid.* **22,** 389 (1972).

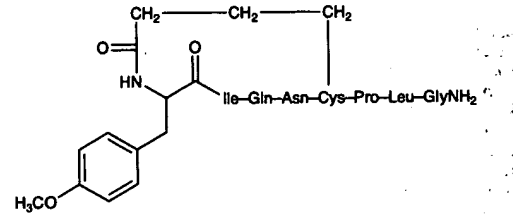


$bp_{0.01}$ 165-170°.

Citrate, $C_{20}H_{31}NO_3 \cdot C_6H_8O_7$, ***UCB-2543, Antees, Calnathal, Carbetane, Cossym, Fustpentane, Germapect, Pencal, Sedotussin, Toclase, Tosnone, Tuclase.*** Crystals, mp 93°. Freely sol in water, chloroform; sol in alcohol, acetone, ethyl acetate. Practically insol in ether, petr ether, benzene.

THERAP CAT: Antitussive.

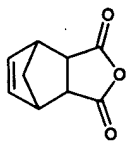
1841. Carbetocin. ***1-Butanoic acid-2-(O-methyl-L-tyrosine)-1-carbaoxytocin;*** 1-butyric acid-2-[3-(*p*-methoxyphenyl)-L-alanine]oxytocin; deamino-2-*O*-methyltyrosine-1-carbaoxytocin; 1-thia-4,7,10,13,16-pentaazacycloeicosane cyclic peptide deriv; 1-desamino-1-monocarba-[2-tyr(OMe)]-OT; (2-*O*-methyltyrosine)deamino-1-carbaoxytocin; d(COMOT); Decomoton; Depotocin. $C_{45}H_{69}N_{11}O_{12}S$; mol wt 988.18. C 54.70%, H 7.04%, N 15.59%, O 19.43%, S 3.24%. Synthetic carba-analog of oxytocin, *q.v.* Prepn: I. Fric *et al., Coll. Czech. Chem. Commun.* **39,** 1290 (1974); J. H. Cort *et al.,* **Ger.** pat. **2,732,175** (1976 to Czech. Akad. Ved.). Chromatographic properties: M. Lebl, *ibid.* **45,** 2927 (1980). Uterotonic and galactogogic activity: T. Barth *et al., ibid.* 3045; T. Barth *et al., ibid.* **46,** 2441 (1981). Pharmacokinetics in lactating sows: N. Cort *et al., Am. J. Vet. Res.* **42,** 1804 (1981). Use in regulation of bovine labor: Z. Veznik *et al., ibid.* **40,** 425 (1979). Effect on milk let-down in sows: N. Cort *et al., ibid.* **43,** 1283 (1982).



Solid from methanol with ether $[\alpha]_D$ −69.0° (c = 0.25 in 1*M* acetic acid).

THERAP CAT (VET): Oxytocic, stimulates milk let-down.

1842. Carbic Anhydride. ***3aα,4,7,7aα-Tetrahydro-4α,7α-methanoisobenzofuran-1,3-dione; cis-endo-5-norbornene-2,3-dicarboxylic anhydride; endo-cis-*** bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic anhydride; 3,6-endomethylene-1,2,3,6-tetrahydro-*cis*-phthalic anhydride; 3,6-endomethylene-Δ^4-tetrahydrophthalic anhydride; nadic anhydride; $C_9H_8O_3$; mol wt 164.16. C 65.85%, H 4.91%, O 29.24%. Prepd by the reaction of maleic anhydride with cyclopentadiene in benzene: Diels, Alder, *Ann.* **460,** 98 (1928). Crystal structure: Destro *et al., Acta Crystallogr.* **25B,** 2465 (1969).

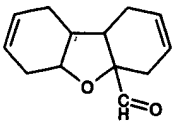


Shiny, orthorhombic crystals from petr ether, mp 164-165°. d 1.417. Converted to equilibrium mixtures with *exo-cis* isomers when heated above mp. Sol in benzene, toluene, acetone, carbon tetrachloride, chloroform, ethanol, ethyl acetate. Slightly sol in petr ether. Reacts with water to form the corresponding acid. Forms the γ-lactone of 5-hydroxy-2,3-norcamphanedicarboxylic acid in 50% H_2SO_4.

1843. Carbidopa. ***S-α-Hydrazino-3,4-dihydroxy-α-methylbenzenepropanoic acid monohydrate; (—)-L-α-hydrazino-3,4-dihydroxy-α-methylhydrocinnamic acid monohydrate;*** α-

R

8271. R-11. *1,5a,6,9,9a,9b-Hexahydro-4a(4H)-dibenzofurancarboxaldehyde;* 2,3,4,5-bis(2-butenylene)tetrahydrofurfural; MGK-11; MGK Repellent 11. $C_{13}H_{16}O_2$; mol wt 204.27. C 76.44%, H 7.90%, O 15.67%. Prepd by heating furfuraldehyde with butadiene and water under pressure: Hillyer, Nicewander, U.S. pat. **2,683,151** (1954 to Phillips Petroleum). Clinical efficacy vs. sand flies: F. P. Fossati, M. Maroli, *Trans. Roy. Soc. Trop. Med. Hyg.* **80,** 771 (1986).



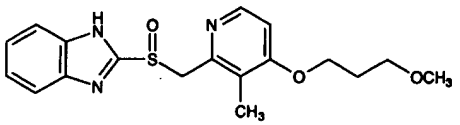
Liquid, bp 307°. d_4^{20} 1.10. mp −80°. n_D^{20} 1.5254. Practically insol in water.

Oxime, mp 97.2°.

Dinitrophenylhydrazone, mp 152.8°.

USE: Insect repellent.

8272. Rabeprazole. *2-[[[4-(3-Methoxypropoxy)-3-methyl-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole;* pariprazole. $C_{18}H_{21}N_3O_3S$; mol wt 359.45. C 60.15%, H 5.89%, N 11.69%, O 13.35%, S 8.92%. Partially reversible gastric proton pump inhibitor. Prepn: S. Souda *et al.,* Eur. pat. **Appl. 268,956;** *eidem,* U.S. pat. **5,045,552** (1988, 1991 both to Eisai). Pharmacology: H. Goto *et al., Arzneimittel-Forsch.* **41,** 635 (1991). Mode of action: M. Morii, N. Takeguchi, *J. Biol. Chem.* **268,** 21553 (1993). HPLC determn in plasma: H. Nakai *et al., J. Chromatog. B* **660,** 211 (1994). Clinical pharmacokinetics: S. Yasuda *et al., Int. J. Clin. Pharmacol. Ther.* **32,** 466 (1994).

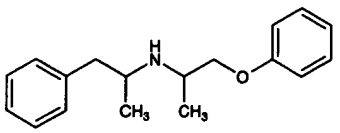


White crystals from CH_2Cl_2/ether, mp 99-100° (dec).

Sodium salt, $C_{18}H_{20}N_3NaO_3S$, *E-3810.* White crystals from ether, mp 140-141° (dec).

THERAP CAT: Antiulcerative.

8273. Racefemine. *(±)-α-Methyl-N-(1-methyl-2-phenoxyethyl)benzeneethanamine; dl-threo-α-methyl-N-(1-methyl-2-phenoxyethyl)phenethylamine; dl-threo-α-*methyl-*N*-(1-phenoxy-2-propyl)phenethylamine; *dl-threo-N-*(1-methyl-2-phenylethyl)-*N*-(2-phenoxy-1-methylethyl)amine; CB-3697. $C_{18}H_{23}NO$; mol wt 269.39. C 80.26%, H 8.61%, N 5.20%, O 5.94%. Smooth muscle relaxant. Prepn from amphetamine and phenoxyacetone with isomer separation: **Neth. pat. Appl. 6,407,309** (1964 to Clin-Byla), *C.A.* **63,** 353c (1965).

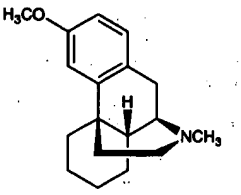


Isomers: From *dl*-amphetamine, a yellow liq, $bp_{0.05}$ 132-135°, was obtained which was separated into isomers I and II. *I-Fumarate:* mp 162°. *I-Hydrochloride:* mp 156-157°. *II-Hydrochloride:* mp 167-168°. From *d*-amphetamine, isomers III, $[\alpha]_D^{21}$ +41° (c = 0.01 in ethanol), and IV, $[\alpha]_D^{22}$ +22° (c = 0.005 in ethanol), were obtained. *III-Fumarate:* mp 164-165°, $[\alpha]_D^{20}$ +19° (c = 0.01 in ethanol). *III-Hydrochloride:* mp 186-187°, $[\alpha]_D^{21}$ +22° (c = 0.01 in ethanol). *IV-Hydrochloride:* mp 160-163°, $[\alpha]_D^{20}$ +22° (c = 0.01 in ethanol). From *l*-amphetamine, isomers V, $[\alpha]_D^{24}$ −24° (c = 0.01 in ethanol), and VI, $[\alpha]_D^{24}$ −41° (c = 0.01 in ethanol), were obtained. *V-Hydrochloride:* mp 189-190°, $[\alpha]_D^{21}$ −22° (c = 0.01 in ethanol). *VI-Fumarate:* mp 164-164.5°, $[\alpha]_D^{22}$ −15° (c = 0.01 in ethanol). *VI-Hydrochloride:* mp 186-187°, $[\alpha]_D^{21}$ −21.5° (c = 0.01 in ethanol).

Fumarate, $C_{22}H_{27}NO_5$, *Dysmalgine.*

THERAP CAT: Antispasmodic.

8274. Racemethorphan. *(±)-3-Methoxy-17-methylmorphinan; dl-cis-*1,3,4,9,10,10a-hexahydro-6-methoxy-11-methyl-2*H*-10,4a-iminoethanophenanthrene; *dl-cis-*1,2,3,9,-10,10a-hexahydro-6-methoxy-11-methyl-4*H*-10,4a-iminoethanophenanthrene; deoxydihydrothebacodine; methorphan. $C_{18}H_{25}NO$; mol wt 271.40. C 79.66%, H 9.28%, N 5.16%, O 5.90%. Prepn: Schnider, Grüssner, **U.S. pat. 2,676,177** (1954 to Hoffmann-La Roche). Prepn of *d*-form: *eidem, ibid.;* Häfliger *et al., Helv. Chim. Acta* **39,** 2053 (1956). Prepn of *l*-form hydrobromide: Corrodi *et al., ibid.* **42,** 215 (1959). Crystal structure and absolute configuration of *d*-form hydrobromide: L. Gylbert, D. Carlstrom, *Acta Crystallogr.* **B,** 2833 (1977).



Hydrobromide, $C_{18}H_{25}NO.HBr$, *Ro-1-5470.* Crystals, mp 124-126°.

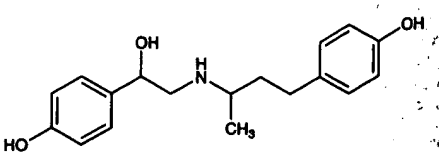
d-Form hydrobromide, *dextromethorphan hydrobromide, demorphan hydrobromide, Ro-1-5470/5, Benylin DM, Canfodion, Cosylan, Hihustan M.* Occurs as the monohydrate, crystals, mp 122-124°. $[\alpha]_D^{20}$ +27.6° (c = 1.5 in water). Approx soly in water: 1.5% at 25°, 5% at 50°, 25% at 85°. Soly (w/w): 25% in 95% ethanol at room temp, 10% in glycerol. Sol in propylene glycol, chloroform. Practically insol in ether. pH of a 1% aq soln: 5.2-6.5. Long range stability of aq solns obtained by adjusting pH within 4-5.6. Reacts with alkalies forming the free base which is practically insol in water.

l-Form hydrobromide, *levomethorphan hydrobromide, Ro-1-5470/6, Ro-1-7788.* Occurs as the dihydrate, crystals, mp 124-126°. $[\alpha]_D^{20}$ −26.3°.

Note: Racemethorphan and levomethorphan are controlled substances (opiates) listed in the U.S. Code of Federal Regulations, Title 21 Part 1308.12 (1995).

THERAP CAT: Antitussive.

8275. Ractopamine. *4-Hydroxy-α-[[[3-(4-hydroxyphenyl)-1-methylpropyl]amino]methyl]benzenemethanol;* 1-(4-hydroxyphenyl)-2-[1-methyl-3-(4-hydroxyphenyl)-propylamino]ethanol; *N*-[2-(4-hydroxyphenyl)-2-hydroxyethyl]-1-methyl-3-(4-hydroxyphenyl)propylamine. $C_{18}H_{23}NO_3$; mol wt 301.39. C 71.73%, H 7.69%, N 4.65%, O 15.93%. β-Adrenergic agonist; repartitioning agent. Prepn (stereochemistry unspecified): J. van Dijk, H. D. Moed, *Rec. Trav. Chim.* **92,** 1281 (1973). Prepn of *R,R*-isomer: J. Mills *et al,* **Eur. pat. Appl. 7,205** (1980 to Lilly). Prepd (not claimed): D. B. Anderson *et al.,* U.S. pat. **4,690,951** (1987 to Lilly). LC determn in animal feeds: M. P. Turberg *et al., J. AOAC Int.* **77,** 840 (1994). Metabolism and tissue residue studies: J. E. Dalidowicz *et al.,* in *ACS Symposium Series* **503,** entitled "Xenobiotics and Food Producing Animals;" D. H. Hutson *et al.,* Eds. (ACS, Washington, DC, 1992) pp 234-243. Effect on growth, carcass characteristics and meat quality in swine: B. E. Uttaro *et al., J. Anim. Sci.* **71,** 2439 (1993). Effect on β-receptor affinity and density in pigs: M. E. Spurlock *et al., ibid.* **72,** 75 (1994).



The Informed Parent
Voice of the Pediatric Medical Center

COUGH SYRUP ABUSE

by Shanna R. Cox, M.D., F.A.A.P.

August 30, 2004

Over the years parents have had to be aware of multiple items that could be abused in the hands of children. Items seemingly as innocuous as rubber glue have been implicated in cases of neurological damage. Air conditioning units are monitored for their frion, another agent that may give a lethal high. Now another product needs to be added to this list. Dextromethorphan, an over-the-counter cough suppressant, is currently a popular drug of abuse. Advertised on Internet sites for delivering a sense of euphoria, this medication is an attractive alternative for many teens. While the routine dose of dextromethorphan is approximately two tablespoons, or an ounce, teens are consuming anywhere from 4-20 fluid ounces in order to produce desired side effects. The easy availability of this cough syrup makes it particularly dangerous.

Dextromethorphan is available as part of many routine cough and cold agents that families typically have in their household. Robitussin DM and Triaminic Cough and Cold are just two examples of common brands that contain this cough suppressant. Teens may first experiment with common over-the-counter preparations to sample the side effects of this medication. More advanced users may seek out dextromethorphan powder, a more concentrated form of the drug that may be suspended without the medicinal taste of cough medicine. Dextromethorphan is an opiod, which puts it in the same class of drugs as heroin and PCP, better known drugs of abuse. In fact, DXM, as it is often referred to, acts on the same receptor in the brain as PCP but with a somewhat lower affinity. Urine toxicology screens usually will screen negative for opiates because of the attenuated receptor affinity, but may show a false positive PCP reading.

High doses of dextromethorphan can produce varied effects. At high levels there may be four phases of intoxication with different side effects. At first users will have an effect similar to alcohol or marijuana intoxication with the addition of a reported increased enjoyment of music. The second phase begins to parallel symptoms classically linked with LSD use, with the user experiencing visual hallucinations, incoordination, and heightened color perception. The last two phases of intoxication reveal DXM's link to PCP as the user

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Our Book Recommendations

What's a Parent to Do?
Straight Talk on Drugs and Alcohol
by Henry David Abraham, M.D.

How to "nip the culprit in the bud". Dr. Abraham offers a concise, no-nonsense, straight forward look at this growing problem. This book empowers parents to head off substance abuse before it gets started.

Island of the Blue Dolphins
by Scott O'Dell

Karana finds herself alone, on a deserted island, after her American Indian tribe has evacuated. This true story tells of an 18 year survival, forging for food, fending off wild dogs,

may develop delusions and psychosis with subsequent mind-body dissociation and possible frank dystonia, or inability to move.

Clearly this over-the-counter medicine has the potential to be just as toxic as better-recognized illicit drugs. For the protection and safety of every family member all medicines should be in a secure location, away from a child's reach. Accidental intoxication of a child is also possible with caregivers who may be unfamiliar with pediatric dosing ranges, or in teens who may not actively seek out the correct dosage. A remedy for this sort of problem is to maintain a list of correct dosages for age and weight. This is maintained along with the more standard emergency contact list that is always visible and easily reachable in the home. As always, attention to your child's activities, whereabouts, and friends is paramount in supervising their growth and development. Note the above signs and symptoms, and actively engage your child in discussion about any concerns you may have. Remember, your pediatrician is available for counsel and discussion, as drug abuse is an evermore-frequent possibility in childhood.

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maintaining sanity. Youngster 9-12 years will find this inspiring. Scott O'Dell received the Newbery Medal for this story.

MAMA
by Kelly Jones; Collages by Ken Kewley

A charming tale of big sister who can interpret baby brother's language. The art work is graphically displayed, bringing chuckles to the reader.

Raising Cain: Protecting the Emotional Life of Boys
by Dan Kindlon, Ph.D. and Michael Thompson, Ph.D.

A deep and earnest look into the lives of the adolescent male. Generally we find them hurt, sad, afraid and silent. They are on the throes of suicide, alcohol or drug abuse, violence and loneliness. This is a look at the destructive emotional miseducation our boys are receiving today.

SADAKO AND THE THOUSAND PAPER CRANES
by Eleanor Coerr

Sadako has leukemia. She must find a way to deal with this devastating news. Turning to her native beliefs she makes a thousnd paper cranes so that the gods will grant her wish--to be well again. Based on a true story. Ages 4-8 years.

Carbetapentane, Phenylephrine, and Pyrilamine

Pronunciation (kay bay ta PEN tane, fen il EF rin, & peer Il a meen)

U.S. Brand Names Tussi-12® D; Tussi-12® DS

Synonyms Phenylephrine Tannate, Carbetapentane Tannate, and Pyrilamine Tannate; Pyrilamine, Phenylephrine Carbetapentane

Therapeutic Category

- Antihistamine
- Antihistamine/Decongestant/Antitussive
- Antitussive
- Decongestant

Use Symptomatic relief of cough associated with respiratory tract conditions such as the common cold, bronchial and chronic bronchitis

Pregnancy Risk Factor C

Pregnancy Implications Reproduction studies have not been conducted with this combination.

Contraindications Hypersensitivity to carbetapentane, pyrilamine, phenylephrine, or any component of the form or within 14 days of MAO inhibitors; breast-feeding; newborns

Warnings/Precautions Use caution with hypertension, cardiovascular disease, increased intraocular pressure, dysfunction, prostatic hyperplasia, or diabetes. Suspension contains tartrazine which may cause allergic-type rea sensitive to this dye; incidence may be increased with concomitant aspirin allergy. Causes sedation; caution mus performing tasks which require alertness (eg, operating machinery or driving). Sedative effects of CNS depressar additive. Use caution in elderly patients, risk of CNS depression may be increased. May cause paradoxical excitat patients.

Adverse Reactions Frequency not defined.

Central nervous system: Drowsiness, sedation

Gastrointestinal: Xerostomia

Overdose/Toxicology CNS depression or stimulation may occur; convulsions have been reported in young chil should be symptomatic and supportive.

Drug Interactions

CNS depressants: Sedative effects may be potentiated.

MAO inhibitors: Anticholinergic effects may be increased and prolonged; avoid use with and within 14 days of tre inhibitors.

Food Interactions

Ethanol: Avoid ethanol (may increase CNS depression).

Stability Store at controlled room temperature of 20°C to 25°C (68°F to 77°F).

Mechanism of Action

Carbetapentane is a nonopioid cough suppressant.

Phenylephrine hydrochloride is a sympathomimetic agent (primarily alpha), decongestant.

Pyrilamine is an H_1-receptor antagonist.

Usual Dosage Oral: Relief of cough:

Children:

2-6 years (Tussi-12® DS): 2.5-5 mL every 12 hours

6-11 years:

Tussi-12® D: $^1/_2$ to 1 tablet every 12 hours

Tussi-12® DS: 5-10 mL every 12 hours

Children ≥12 years and Adults (Tussi-12® D): 1-2 tablets every 12 hours

Dietary Considerations Tussi-12® DS (suspension) contains tartrazine which may cause allergic-type reactions sensitive to this dye.

Dosage Forms

Suspension (Tussi-12® DS): Carbetapentane tannate 30 mg, pyrilamine tannate 30 mg, and phenylephrine tann mL (120 mL) [contains benzoic acid and tartrazine; strawberry-currant flavor; packaged with oral syringe]

Tablet (Tussi-12® D): Carbetapentane tannate 60 mg, pyrilamine tannate 40 mg, and phenylephrine tannate 10

WHAT ARE THE SPECIFIC DRUGS AND REMEDIES FOR TREATING A MIGRAINE ATTACK?

Specific Treatments for Mild Migraine

Excedrin Migraine. Some patients with mild migraines respond well to over-the-counter painkillers, particularly if they are administered at the very first warning of an impending attack. Excedrin Migraine, which contains acetaminophen, aspirin, and caffeine, is the first over-the-counter medication to be considered effective for temporary relief of migraines. Studies have reported significant relief in nearly 70% of patients. It may also help menstrual migraines.

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). NSAIDs are also first-line drugs tried for mild to moderate migraines. They are not very effective when used alone against severe migraine headache. Some experts suggest that the effect that the migraine process has on the gastrointestinal (GI) tract may prevent the absorption of NSAIDs. Some studies reporting benefits for specific NSAIDs include the following:

- Aspirin, ibuprofen (Advil Migraine), and naproxen (Anaprox, Aleve) are all available over the counter, and may have some benefits for mild migraine. Naproxen appears to be more effective than other NSAIDs. An investigative ibuprofen gel that has been effective in relieving headaches in early studies.
- A study of children who had migraines compared ibuprofen and acetaminophen. Acetaminophen worked faster, but after three hours, ibuprofen was more effective. Parents of children with migraines should consult with their physicians about using a combination of these drugs.
- Researchers have combined a high-dose NSAID (equivalent to 900 mg of aspirin) with metoclopramide (Reglan), a drug that prevents nausea and vomiting. Several studies show this combination is equal to oral sumatriptan and superior to DHE, two standard migraine drugs. People should not take high doses of NSAIDs without some protective agent since they can cause severe gastrointestinal distress.
- In one study, an NSAID combination, diclofenac-potassium (Cataflam), was as effective as sumatriptan, a standard migraine drug. Cataflam worked more rapidly and helped reduce nausea. The combination is not appropriate for people allergic to aspirin or at risk for bleeding.
- Injectable NSAIDs, particularly ketorolac, are proving in some cases to be equally or more effective than powerful migraine medications used for severe and persistent migraines. It should be noted that ketorolac has a higher risk for gastrointestinal bleeding than many other NSAIDs.

New NSAIDs, called selective COX-2 inhibitors include celecoxib (Celebrex), rofecoxib (Vioxx), and meloxicam (Mobic). These agents may allow high doses without the accompanying gastrointestinal side effects.

Cooling Pads. Cooling pads may help during an attack. Some products (Migraine Ice, TheraPatch Headache Cool Gel) employ a pad containing a gel that cools the skin for

up to four hours and can be placed on the forehead, temple, or back of the neck.

Ginger. In general, herbal medicines should never be used by children or pregnant or nursing women without medical counsel. One exception may be ginger, which has no side effects and can be eaten in powder or fresh form, as long as quantities are not excessive. Some people have reported less pain and frequency of migraines while taking ginger, and children can take it without danger.

Triptans

Triptans (also referred to as serotonin agonists) help maintain serotonin levels in the brain and so specifically target one of the major components in the migraine process. Triptans are the most important migraine agents currently available and are now recommended as first-line agents for many adult patients with moderate to severe migraines when NSAIDs are not effective. Patient satisfaction is high with these agents and they have the following benefits:

- They appear to be effective for most migraine patients.
- They are beneficial for patients with combination tension and migraine headaches.
- They may be effective for preventing menstrual migraines.
- They do not have the sedative effect of other migraine drugs.
- Withdrawal after overuse appears to be of shorter duration and is less severe than with other migraine medications.

Brands and Success Rates. Brands and Success Rates. Sumatriptan (Imitrex) was the first drug specifically developed for use against migraine. Newer oral triptans include zolmitriptan (Zomig), naratriptan (Naramig, Amerge), rizatriptan (Maxalt), almotriptan (Axert), frovatriptan (Frova), eletriptan, and avitriptan.

Sumatriptan has the longest track record and is the most studied. It is can be administered orally in table form, as an injection, or as nasal spray. Injected sumatriptan works the fastest, but is inconvenient and causes pain at the injection site. The nasal spray form bypasses the stomach and is absorbed more quickly than the oral form. Some patients report relief as soon as 15 minutes after administration. The spray may leave a bad taste and it tends to be less effective when a person has nasal congestion from cold or allergy. Sumatriptan has proven to bring rapid relief to most migraine sufferers. Unfortunately, recurring headaches with sumatriptan develop within the first 24 hours in 20% to 40% of people who have taken the drug.

Studies on the newer agents have reported pain relief within two hours in between 60% and 91% of patients. Comparison studies with sumatriptan are suggesting that the newer agents have fewer side effects and are superior to sumatriptan for providing immediate, sustained, and consistent pain relief. Recurrence rates are also lower. Of these agents, almotriptan is emerging as being both effective and having fewer side effects, particularly chest pain, than other triptans. It may prove to be one of the most cost effective of these agents. Naratriptan also has few side effects and has been referred to as the "gentle" triptan.

Combinations of triptans plus NSAIDs may be helpful in preventing recurrence.

Side Effects. Many of the newer triptans may have fewer severe side effects than sumatriptan. Side effects of most triptans, however, can include the following:

- Nausea.

- Dizziness.
- Muscle weakness.
- Heaviness, pain or both in the chest. (About 40% of patients taking sumatriptan experience these symptoms and they are major factors in discontinuing the drug. Newer agents, such as almotriptan, produce fewer chest symptoms.)
- Tingling and numbness in the toes.
- Rapid heart rate.
- Other effects include a warm sensation and discomfort in the ear, nose, and throat.

Complications of Triptans. The following are potentially serious problems.

- Complications on the Heart and Circulation. Triptans narrow (constrict) blood vessels. Because of this effect, very rarely spasms in the blood vessels may occur and cause serious side effects, including stroke and heart attack. Such events are not only rare but occur primarily in patients with an existing history or risk factors for these conditions.
- Serotonin Syndrome. Triptans also affect serotonin and so people taking antidepressants that increase serotonin levels (which are most antidepressants) should avoid taking both. The effects of such combinations may cause a so-called serotonin syndrome, which causes mental changes, restlessness, tremor, chills, sweating, and colitis. Some physicians believe, however, that the risk for the syndrome from taking both classes of drugs is very small.

The following groups should avoid triptans or take them with caution and only with the advisement of a physician:

- Anyone with a history or with any risk factors for stroke, uncontrolled diabetes, high blood pressure, or heart disease.
- People taking antidepressants that increase serotonin levels.
- Pregnant women. Studies on the effects of triptans in this group are limited. One study suggested a higher incidence of preterm deliveries in pregnant women taking sumatriptan. No higher rates of still births or birth defects were reported. In general, pregnant women should avoid any medications if possible.
- Children and adolescents. They may be safe, but controlled studies are needed to confirm this. (Triptans should not, in any case, be the first-line treatment for children.) [*See Box* Migraines in Children.]
- People with basilar or hemiplegic migraines. (Triptans are not indicated for these migraineurs.)

Ergotamine (Ergot)

Drugs containing ergotamine (commonly called ergots) constrict smooth muscles, including those in blood vessels, and are useful for migraine.

Forms of Ergotamine.

- Dihydroergotamine (DHE) is an ergot derivative. It is administered by injection, which can be performed at home. A nasal spray form of DHE (Migranal) may have fewer side effects than the injection. Dihydroergotamine has stopped migraine attacks in up to 90% of cases and is often effective against menstrual migraines.

- Ergotamine itself is available in oral tablets (Ergomar, Wigraine, Ercaf) and in rectal suppositories (Cafergot). Cafergot, Wigraine, and Ercaf contain caffeine.

- An ergotamine inhaler is being investigated.

Side Effects. Side effects of ergotamine include the following:

- Nausea.

- Dizziness.

- Tingling sensations.

- Muscle cramps.

- Chest or abdominal pain.

- The following are potentially serious problems:

- Toxicity. Ergotamine is toxic at high levels.

- Complications on the Heart and Circulation. It also causes persistent blood vessel contractions, which may pose a danger for people with heart disease or risk factors for heart attack or stroke.

The following patients should avoid ergots:

- Pregnant women.

- People over 60.

- Those with serious, chronic health problems, particularly those of the heart and circulation.

Lidocaine

Nasal drops containing lidocaine, a local anesthetic, can provide effective pain relief within 15 minutes for many migraine sufferers. One case report suggests that taking it during the aura phase may offer significant protection against developing the full-blown headache. It has certain downsides:

- It is rather difficult to administer. Patients must be lying down with their head dangling.

- The headache often relapses in an hour, and other drugs must then be used.

- Side effects include unpleasant taste, burning sensation, and facial numbness.

However, the drug does not cause drowsiness or heart rhythm disturbances as some other migraine treatments do. And its fast effectiveness and safety make it a promising first drug during a migraine attack. It should not be used for any other form of headache.

Opiates

If the pain is very severe and does respond to other agents, physicians may try pain killers containing opiates (e.g., morphine, codeine, meperidine [Demerol], or oxycodone [Oxycontin]). Butorphanol is an opiate in nasal spray form that may be useful as a rescue treatment when others fail. A number of such opiates use combinations of NSAIDs (ibuprofen or aspirin) or acetaminophen with an opioid. One study reported that about half of patients who start opioid therapy for migraine respond well and the benefits persist over time.

Side Effects. Side effects for all opioids include drowsiness, impaired judgment, nausea, and constipation. Addiction is a risk. Such drugs should not be prescribed for patients at risk for drug abuse, including those with personality or psychiatric disorders.

Agents Used to Prevent Nausea and Vomiting

Metoclopramide (Reglan) is used in combinations with other agents to treat the nausea and vomiting that occurs with other drugs and with the condition itself. In fact, in one study using only aspirin with metoclopramide had some significant effect on the migraine itself. This and other anti-nausea drugs, such as domperidone (Motilium) may also help the intestine absorb the migraine medications.

Investigative Treatments

Nerve Protecting Agents. These investigative agents block nerve pathways in the brain that are responsible for over-exciting nerve cells. One agent called LY293558 is known as an AMPA glutamate receptor antagonist and is showing promise in early trials.

Intra-Oral Vasoconstriction Device (IVC). An interesting investigative approach called the intra-oral vasoconstriction device (IVC) is based on the idea that many headaches are associated with inflammation in the areas above the upper molar teeth. This creates swelling and puts pressure on the maxillary nerves, which are behind the cheekbones. IVC employs hollow tubes containing circulating ice water that the patient holds against areas in the mouth thought to be inflamed. A small early study reported that the device was as effective as sumatriptan in relieving headache pain. In addition, it appeared to relieve nausea.

Review Date: 6/30/2002

Reviewed By: Harvey Simon, MD, Editor-in-Chief, Associate Professor of Medicine, Harvard Medical School; Physician, Massachusetts General Hospital

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Opioids (narcotics)

By Mayo Clinic staff

Opioids are prescription medications and are regulated as controlled substances by the Drug Enforcement Administration. A doctor must have a special license in order to prescribe these drugs.

Opioids are often used to relieve pain from cancer, terminal illness, severe injury or surgery. Pain control after surgery is especially important. The sooner you're active, the less the risk of complications due to inactivity, such as pneumonia or blood clots.

Opioids, sometimes called narcotics, come in several forms. Some are natural compounds derived from the opium poppy. These are called opiates. There are also synthetic opioids that work in similar ways. *Opioids* include both these natural and synthetic forms and is the preferred term.

Your body contains naturally occurring chemicals called opioid peptides, which are similar to the narcotic morphine. One theory behind several complementary and alternative treatments for pain is that they activate these naturally occurring opioid peptides in your brain and spinal cord.

Commonly used opioids

Frequently prescribed opioids include the following:

- Codeine
- Fentanyl (Duragesic)
- Hydrocodone
- Hydromorphone (Dilaudid)
- Levorphanol (Levo-Dromoran)
- Meperidine (Demerol)
- Methadone (Dolophine)
- Morphine (MS Contin, Oramorph SR, others)
- Oxycodone (OxyContin)
- Oxymorphone (Numorphan)
- Propoxyphene (Darvon)

Side effects of opioids include mild dizziness, drowsiness, sedation and unclear thinking. These can make it unsafe for you to drive or operate machinery. Sometimes you can do things to manage the dizziness. For example, you might feel better after lying down for a while. Getting up slowly from a sitting or lying position also can help. If you experience severe dizziness or drowsiness, get emergency care. Also go to the emergency room if you feel extreme nervousness, severe weakness, cold, clammy skin or have trouble breathing.

Other side effects of opioids include constipation, nausea and vomiting. Ask your doctor or pharmacist about ways to manage these problems.

The medical debate over opioids

The goal of treatment of acute pain is to relieve pain immediately, usually with medications. Unrelieved pain has many negative effects, such as delayed recovery from surgery and decreased immunity to disease.

For people with chronic pain, the goals of treatment are more complex. Pain relief is important, but so is the ability to function at work and to be able to enjoy social and leisure activities.

The goal of pain relief and the goal of improved function are sometimes in

conflict. Opioids are powerful pain relievers. When taken in small amounts for short periods, they generally cause only minor side effects. But when taken in increasing doses for several weeks or months, these side effects can become bothersome.

Opioids can also produce what is sometimes described as rebound pain. For instance, some opioids have an effect that lasts only a few hours. The pain can return as these short-acting medications wear off or when they are withdrawn from your treatment plan.

Ironically, opioids can also cause changes in your nervous system that may actually heighten your perception of pain and make you feel more uncomfortable. This condition is called hyperalgesia.

Because opioids have so many effects, some good and some bad, and there is concern about their lack of effectiveness for treating some types of pain, some doctors restrict the use of opioids when treating chronic pain. They may also be uneasy about possible long-term side effects, which can interfere with rehabilitation and lead to more doctor visits and hospital stays. They also cite the risk of physical dependence and addiction to opioids.

Other doctors take the position that withholding opioids leads to unnecessary pain and suffering — that the side effects of opioids can be managed and that the risk of addiction is overblown. This view holds that legal and medically supervised use of opioids has little in common with illegal use of such drugs.

Getting clear about the risk of addiction

The issue of addiction is important. However, three terms relevant to discussion of this topic are often used inappropriately: *tolerance*, *physical dependence* and *addiction*. Often used synonymously, these words, in fact, point to three different conditions:

- **Tolerance** happens when the initial dose of an opioid loses its effectiveness over time, calling for higher doses of the drug to produce the desired effect.
- **Physical dependence** occurs when your body adapts to a drug. When the drug is withdrawn, you may then experience anxiety, tremors and other physical withdrawal symptoms.
- **Addiction** is a primary disease marked by cravings for a drug and compulsive use of that drug despite repeated, harmful consequences.

With time, people who take opioids are likely to develop tolerance and even physical dependence. However, this doesn't mean that they are addicted. Addiction results from many factors — genetic, psychological and environmental — and often takes years to develop. Exposure to opioids is only one factor. Most people treated with opioids never become addicted.

Sometimes people with chronic pain act in ways that are mistakenly for addiction. These individuals may focus on maintaining their supply of opioids or closely watch the clock to make sure they take their next dose of medication. Often these are not addictive behaviors but pseudoaddiction — behaviors that stop once people get satisfactory pain relief.

Considering opioids in your pain treatment

Despite the debate over the use of opioids, they can be a key part of your treatment plan. Before prescribing these drugs, your doctor will give you a thorough physical exam and take a detailed medical history. The results will help determine whether opioids are right for you.

When thinking about opioids, consider your full range of options. Ask about the possibility of combining opioids with simple analgesics for maximum pain relief.

Also, compare the benefits of short-acting and sustained-release medications, and discuss whether you should take opioids on a regular schedule or simply on an as-needed basis. In addition, before taking opioids, you may want to get a second opinion.

Finally, after you start taking an opioid, compare your function and activity levels with how you were functioning before you began taking the medication. You'll want to see a marked improvement before deciding to continue using the medication long term.

Related Information

- Narcotic Analgesics— For Pain Relief (Systemic)
- Drug addiction
- Drugs & Supplements
- Pain Management Center

November 22, 2002

PN00042

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Introduction

Opioids are potentially addictive narcotic analgesics that act primarily on the central nervous system. Morphine and codeine are opiates (natural opioids derived from the opium poppy). The illicit substance heroin is an opiate obtained by chemically altering morphine. Synthetic opioids include Demerol® and Talwin®. Methadone is another synthetic opioid that is commonly used in the treatment of heroin addiction. All opioids are addictive to some degree and have the potential for abuse.

Heroin, in different forms, can be inhaled (snorted) or smoked. Most commonly it is injected under the skin or into a vein (mainlining). Synthetic narcotics usually come in pill form, but they can also be dissolved and injected. Generally, opioids relieve pain, cause mood fluctuations, alter brain activity, cause drowsiness, depress breathing, and slow digestive functioning. As tolerance to the psychoactive effects develops, larger doses are needed to produce the same effects. Regular use results in severe physical dependence.

The use of opioids during pregnancy increases the risk of medical and obstetric complications, potentially affecting both the woman and the fetus. Opioids cross the placenta and enter the fetal bloodstream. The level of opioids in the fetal bloodstream is lower than in the mother's, but drug concentrations are often high enough to harm the fetus. For example, alternating between intoxication and withdrawal can result in an unstable intrauterine environment, which can be fatal to the fetus.

Unfortunately, heroin use often coincides with other negative lifestyle factors that can compound the physical and psychosocial health problems of the opioid-dependent mother and the baby. These factors include:

- poor living conditions, poverty, lack of education, and homelessness;
- erratic lifestyle with poor nutrition and exercise habits, and high stress;
- concurrent medical problems such as sexually transmitted

diseases and AIDS (acquired immune deficiency syndrome);
- multiple drug use;
- the mother being under 15 years of age; and
- inadequate prenatal care.

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Effects on Fertility

Opioid use increases amenorrhea (abnormal absence of menstrual periods) and menstrual irregularity, thus interfering with fertility. Also, the lifestyles of some heroin addicts (e.g., prostitution) often result in sexually transmitted diseases (STDs) and pelvic inflammatory disease (PID), both of which can impair fertility.

Nonetheless, pregnancy is neither impossible nor uncommon. Unfortunately, the early signs of pregnancy, such as nausea and fatigue, are often misinterpreted as heroin withdrawal symptoms. This may delay the confirmation, and interfere with the dating of pregnancy. Worse, the pregnant woman, believing she is experiencing withdrawal, may increase her drug use. As the drug use increases, the risks of obstetrical and medical complications also increase.

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Effects During Pregnancy and Delivery

Heroin addicts have an increased risk of complications during pregnancy, primarily because of alternating toxic and withdrawal states in the pregnant woman. Possible complications with the pregnancy include: abruptio placenta (premature separation of the placenta from the uterus), eclampsia (a life-threatening condition involving high blood pressure and seizures), placental insufficiency (insufficient blood circulation within the placenta), breech presentations, premature labour and birth (which occurs in approximately half of all deliveries), ruptured membranes, and Caesarean sections. Since opioid drugs are readily distributed to the fetus, they can exert profound effects on fetal EEG (brain wave patterns), breathing activity, and glucose (sugar) regulation. There is also an increased likelihood of stillbirths and fetal distress (indicated by meconium staining), and aspiration pneumonia in the newborn. Research has shown that nearly half of women who are opioid dependent can experience anemia, diabetes, heart disease, pneumonia, or respiratory distress during pregnancy.

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Effects on the Newborn

To date, none of the opioid drugs, including heroin and methadone, have been shown to produce physical birth defects in babies, although some research has found higher than usual rates of visual defects (i.e. strabismus). The most consistently reported effect on newborns is intrauterine growth retardation (IUGR) resulting in smaller-than-normal head size and low birth weight. It appears that infants born to methadone-maintained women who receive good prenatal care have relatively higher birth weights than do babies born to women who abuse heroin during pregnancy and have no prenatal care.

When opioids are taken during pregnancy, the fetus becomes physically dependent and usually undergoes opioid withdrawal after birth. It is estimated that 60-70% of infants born to mothers using heroin or methadone experience neonatal abstinence syndrome. Neonatal abstinence syndrome (NAS) primarily affects an infant's central nervous system. Gastrointestinal tract problems are also common. The symptoms of withdrawal in newborn babies can included: excessive sucking, muscle spasms, irritability, sweating, fever, seizures, breathing problems, high-pitched crying, disturbed sleep and feeding, stuffy nose, sneezing, hiccups, vomiting, and diarrhea. Symptoms usually develop 48 to 72 hours after birth, but may take up to four weeks to appear. NAS symptoms typically begin to subside after one week, but they have been known to persist for months in some babies. Factors determining the severity of NAS experienced by the baby are: the types of substances used by the mother, the timing of dose prior to delivery, the difficulty of labour, the amounts of anaesthetic and analgesic used during labour, the maturity and nutrition of the infant, and pre-existing diseases in the baby.

Many babies born to heroin-addicted moms have serious medical problems. Primarily resulting from prematurity, these medical problems include brain hemorrhages, hyaline membrane disease of the lungs, and respiratory distress syndrome. Statistically, children born to heroin-addicted mothers are also at higher risk of perinatally transmitted human immunodeficiency virus (HIV) infections and sudden infant death syndrome.

Although infants born to mothers taking prescribed methadone may show signs of physical dependence, they can be treated easily and safely in the nursery. Research has also demonstrated that the effects of in utero exposure to prescribed methadone are relatively benign.

Women who are on a methadone program have fewer complications during pregnancy and childbirth and are generally healthier than those who are using heroin. This is probably due to a combination of clean, controlled drug use, and easier access to medical/prenatal care, as well as easing some of the stresses caused by the need to raise money to buy drugs. Methadone still crosses the placenta, so, if taken, some will reach the baby. There is some evidence of a reduction in fetal and obstetric complications with methadone. Babies cope better with a controlled and constant drug environment.

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Effects During Breastfeeding

Opioids are transmitted to the baby via breast milk, although research shows that exposure levels are lower than prenatal exposure levels. Breastfeeding by motivated mothers in a supervised methadone treatment program may be safe, provided several conditions are in place:

- the mother is on a well-controlled, stable dosage;
- the mother is in good health with adequate nutrition;
- the mother is not infected with HIV, tuberculosis, or hepatitis B; and
- she is not using alcohol or other drugs.

There is some concern about breastfeeding beyond two to six months due to the amount of methadone that may be transmitted. Close monitoring of the baby's responses and the mother's potential for illicit drug use are required.

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Long-Term Effects

While research on animals suggests that exposure to any drug in utero has long-term physiological effects across the entire life span, there has been very little research on the long-term effects of intrauterine opioid exposure in people. To date, research into long-term effects has been inconclusive, leading some researchers to suggest that if there are long-term effects, they may be quite subtle or may take years to appear. Researchers generally concur that predicting the developmental outcome of a child exposed to a drug in utero is difficult because development also depends on environmental factors (such as other drug use and the home environment), as well as on the child's own constitutional makeup. It is best to focus on a child's current abilities and environmental situation when making an assessment or determining interventions.

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Recommended Treatment

Detoxification or slow medical withdrawal from either heroin or methadone is generally avoided during pregnancy due to risk of death of the fetus. The cycling between intoxication and withdrawal is potentially more detrimental to the fetus than the maintenance of constant blood levels, whatever the level.

While drug use during pregnancy is regarded as harmful, prenatal detoxification is considered even more dangerous and permissible only with very slow reduction in mid trimester. If withdrawal is attempted, it should be done with intensive psychosocial support and regular patient and fetal monitoring. However, the view that women should receive maintenance throughout pregnancy is still widely held.

The primary goals of methadone maintenance for the pregnant woman are to stabilize her physically and socially, and to prevent the stressful effects of drug withdrawal on the fetus. A "full blocking dose" of methadone - that is, the minimum dose that will prevent withdrawal symptoms from developing between doses - provides physical stability.

A more recent, secondary goal of methadone maintenance is to reduce intravenous drug use, thereby reducing the risk of HIV infection. Many researchers report other significant benefits of "enhanced" methadone maintenance programs. In addition to simple administration of methadone, enhanced or comprehensive methadone maintenance programs may involve psychosocial and addictions counselling and prenatal care. Benefits of enhanced programs include: better prenatal care resulting in lower obstetric and fetal complications, improved maternal nutrition, decreased criminal activity, and greater possibility of psychosocial rehabilitation.

If pregnancy occurs while the woman is already on methadone maintenance, treatment can continue, although the dose may have to be altered as the pregnancy progresses. However, if the woman is not on methadone, the first step is to determine the minimum appropriate dose to block withdrawal. As this can be a difficult process, hospitalization is recommended to permit close monitoring of the mother and the fetus for a few days. If hospitalization is not possible, research suggests that daily monitoring in a physician's clinic is appropriate.

As pregnancy progresses, the metabolism of methadone changes and it may become necessary to increase the methadone dosage. It has been found that traditional, single-dose treatment significantly influences the behaviour of the fetus. Behavioural changes include abnormally increased activity before treatment and significant depression in activity after treatment. While this is not necessarily indicative of fetal withdrawal, it is not normal behaviour. Some research has found that providing a split dose of methadone, twice per day, helps normalize fetal activity. For this reason, split-dose methadone treatment may be considered when single-dose treatment produces withdrawal symptoms in the mother, or when abnormal fetal activity patterns are evident.

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The Importance of Awareness During Pregnancy

Potential parents need to be informed about the effects that opioid use can have on fertility, pregnancy, and childbirth. They also need to know about potential increased risks to the baby's health over the longer term. During pregnancy, women are often more receptive to health-related information and are motivated to change their drug use behaviour. Research shows that even cutting down drug use during pregnancy can significantly reduce risks. When drug problems are identified and successfully handled during pregnancy, the woman's physical and mental health is improved, and the capacity for healthy childbearing and childrearing is also increased.

For more information, contact your local AADAC office**, or call** 1-866-33AADAC**.**

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Prescription Drug Information > Dextromethorphan

DEXTROMETHORPHAN - ORAL LIQUID

(dex-trow-meth-OR-fan)

COMMON BRAND NAME(S): Benylin, Tussin Pediatric, Vicks 44

DEXTROMETHORPHAN USES: Dextromethorphan is a cough suppressant used to relieve a dry, hacking cough.

HOW TO USE DEXTROMETHORPHAN: Take this medication by mouth as prescribed. Do not increase your dose or take this more often than directed.

DEXTROMETHORPHAN SIDE EFFECTS: Dizziness, drowsiness, nausea, vomiting, or stomach ache may occur the first several days as your body adjusts to the medication. If any of these effects continue or become bothersome, inform your doctor. To avoid dizziness and lightheadedness when rising from a seated or lying position, get up slowly. Also limit your intake of alcoholic beverages which will aggravate these effects. Notify your doctor if you develop: chest pain, a rapid pulse, nervousness, confusion. If you notice other effects not listed above, contact your doctor or pharmacist.

DEXTROMETHORPHAN PRECAUTIONS: Tell your doctor if you have: lung problems (e.g., asthma, emphysema), allergies (especially drug allergies). This medication should be used only if clearly needed during pregnancy. Discuss the risks and benefits with your doctor. Since small amounts of this medication are found in breast milk, consult your doctor before breast-feeding.

DEXTROMETHORPHAN DRUG INTERACTIONS: Tell your doctor of any over-the-counter or prescription medication you use, especially of: MAO inhibitors (e.g., furazolidone, linezolid, phenelzine, selegiline, tranylcypromine). Do not start or stop any medicine without doctor or pharmacist approval.

DEXTROMETHORPHAN OVERDOSE: If overdose is suspected, contact your local poison control center or emergency room immediately.

NOTES: If the cough worsens, last for longer than one week or is accompanied by a high fever, notify your doctor.

MISSED DEXTROMETHORPHAN DOSE: If you miss a dose, take it as soon as remembered; do not take it if it is near the time for the next dose, instead, skip the missed dose and resume your usual dosing schedule. Do not "double-up" the dose to catch up.

DEXTROMETHORPHAN STORAGE: Store at room temperature between 59 and 86 degrees F (15 and 30 degrees C) away from heat and light. Do not store in the bathroom.

Xanax Xenical Zetia
Zithromax Zocor Zofran
Zoloft Zyban Zyprexa Zyrtec

Drug Information Organized Alphabetically

Use our **A to Z drug directory** for drug information:
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Find! Site Map

Dextromethorphan hydrobromide

Dextromethorphan hydrobromide

Dextromethorphan hydrobromide (dex-troh-meth-**OR**-fan) Balminil DM Children* Balminil DM Syrup* Benylin DM Benylin DM for Children Children's Hold Delsym Drixoral Cough Liquid Caps* Hold DM Koffex DM Children* Koffex DM Syrup* Novahistex DM* Novahistine DM* Pertussin CS Pertussin ES Robitussin Cough Calmers Robitussin Pediatric St. Joseph Cough Suppressant Scot-Tussin DM Cough Chasers Sucrets Cough Control Suppress Triaminic DM* Triaminic DM Long Lasting For Children* Trocal Vick's Formula 44 Vick's Formula 44 Pediatric Formula **(OTC)**

Classification: Nonnarcotic antitussive

Action/Kinetics: Selectively depresses the cough center in the medulla. Dextromethorphan 15-30 mg is equal to 8-15 mg codeine as an antitussive. Does not produce physical dependence or respiratory depression. Well absorbed from GI tract. **Onset:** 15-30 min. **Duration:** 3-6 hr. The sustained liquid contains dextromethorphan plistirex equivalent to 30 mg dextromethorphan hydrobromide per 5 mL.

Uses: Symptomatic relief of nonproductive cough due to colds or inhaled irritants.

Contraindications: Persistent or chronic cough or when cough is accompanied by excessive secretions. Use during first trimester of pregnancy unless directed otherwise by physician. Use in children less than 2 years of age.

Special Concerns: Use with caution in clients with nausea, vomiting, high fever, rash, or persistent headache.

Side Effects: *CNS:* Dizziness, drowsiness. *GI:* N&V, stomach pain.

Overdose Management: *Symptoms:* **Adults:** Dysphoria, slurred speech, ataxia, altered sensory perception. **Children:** Ataxia, ***convulsions, respiratory depression.*** *Treatment:* Treat symptoms and provide support.

Drug Interactions: Use with MAO inhibitors may cause nausea,

hypotension, hyperpyrexia, myoclonic leg jerks, and coma.

How Supplied: *Concentrate:* 40 mg/5 mL; *Liquid:* 3.5 mg/5 mL, 5 mg/5 mL, 7.5 mg/5 mL, 15 mg/5 mL; *Lozenge/troche:* 2.5 mg, 5 mg, 15 mg; *Suspension, Extended Release:* 30 mg/5 mL; *Syrup:* 3.5 mg/5 mL, 5 mg/5 mL, 7.5 mg/5 mL, 10 mg/5 mL, 15 mg/5 mL, 20 mg/15 mL; *Tablet:* 15 mg

Dosage

•Capsules, Liquid, Lozenges, Syrup, Concentrate, Tablets
Antitussive.
Adults and children over 12 years: 10-30 mg q 4-8 hr, not to exceed 120 mg/day; **pediatric, 6-12 years:** either 5-10 mg q 4 hr or 15 mg q 6-8 hr, not to exceed 60 mg/day; **pediatric, 2-6 years:** either 2.5-7.5 mg q 4 hr or 7.5 mg q 6-8 hr of the syrup, not to exceed 30 mg/day.
•Sustained-Release Suspension *Antitussive.*
Adults: 60 mg q 12 hr. **Pediatric, 6-12 years:** 30 mg q 12 hr, not to exceed 60 mg/day; **pediatric, 2-6 years:** 15 mg q 12 hr, not to exceed 30 mg/day.

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Heritage Information Systems, Inc.

Drug Monograph

Drug/Drug Class: Tanafed DMX™ Suspension

Prepared for: Missouri Medicaid

Prepared by: Heritage Information Systems, Inc.

☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose: The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, or require prior authorization for use.

Dosage Forms & Manufacturer: Tanafed DMX™ Suspension, manufactured for First Horizon Pharmaceutical, contains 2.5mg of dexchlorpheniramine tannate, 75mg of pseudoephedrine tannate and 25mg of dextromethorphan tannate per 5mL (one teaspoonful).

Summary of Findings: Tanafed DMX™ Suspension is an antihistamine/decongestant/cough suppressant combination product indicated for the relief of nasal congestion and pressure, itchy nose, throat and eyes, sneezing, runny nose and cough secondary to the common cold, sinusitis and upper respiratory allergies. Currently, there are numerous antihistamine/decongestant/cough suppressant products available on the market. Pricing of Tanafed DMX™ Suspension is not favorably priced when compared to other similar agents.

Status Recommendation: ☒ Prior Authorization (PA) Required ☐ Open Access

Type of PA Criteria: ☐ Increased Risk of ADE ☒ Non-Preferred Agent ☐ Appropriate Indications ☐ PA Not Required

Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug or not (open access). While prescription expenditures are increasing at double-digit rates, payors are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction

Tanafed DMX™ Suspension is an antihistamine/decongestant/cough suppressant combination product.[1]

Dosage Form(s)

Per 5mL (one teaspoonful), Tanafed DMX™ Suspension contains:

- 2.5mg of dexchlorpheniramine tannate
- 75mg of pseudoephedrine tannate
- 25mg of dextromethorphan tannate.[1]

Manufacturer

First Horizon Pharmaceutical, Alpharetta, GA[1]

Indication(s)

Tanafed DMX™ Suspension is indicated for the relief of nasal congestion and pressure, itchy nose, throat and eyes, sneezing, runny nose, and cough secondary to the common cold, sinusitis and upper respiratory allergies.[1]

Clinical Efficacy (mechanism of action/pharmacology, comparative efficacy)

Dexchlorpheniramine tannate is the dextro-isomer and twice as active (based on a weight basis) as chlorpheniramine. Like chlorpheniramine, it competitively inhibits histamine at H_1 receptor sites, which leads to vascular, respiratory and gastrointestinal smooth muscle constriction. In addition to antihistamine effects, dexchlorpheniramine also has anticholinergic properties, thus causing a drying effect.[1]

Pseudoephedrine tannate is an alpha$_1$-adrenergic agonist that constricts the blood vessels in the nasal mucous membrane leading to improved drainage.[2]

Dextromethorphan tannate, a derivative of levorphanol, is an antitussive agent. Unlike levorphanol, it does not have significant analgesic properties and does not suppress respiration at normal doses. Dextromethorphan is comparable to codeine in its cough suppressing properties, which is due to its central action on the cough center in the medulla.[1,4]

Adverse Effects

Dexchlorpheniramine tannate[1,3] – Sedation, CNS impairment, dry mouth and eyes, urinary retention

Pseudoephedrine tannate[1,2] – Elevated blood pressure, palpitations, loss of appetite, tremor, sleep disturbance

Dextromethorphan[1,4] – gastrointestinal upset, drowsiness, dizziness

Drug Interactions

Dexchlorpheniramine tannate[1,3] –
CNS depressants – Additive CNS effects may occur.
MAO inhibitors – Patients may experience increased anticholinergic and sedative effects of dexchlorpheniramine. Concomitant use may also produce severe hypotension.

Pseudoephedrine tannate[1,2] –
Methyldopa, guanethidine and reserpine – Patients may develop hypertension due to increased pressor response.
MAO inhibitors – Patients may develop severe headache, hypertension and hyperpyrexia, which may lead to a hypertensive crisis.

Dextromethorphan tannate[4] –
MAO inhibitors – Patients may develop hypotension, hyperpyrexia, nausea, myoclonic leg jerks and coma following coadministration.
Quinidine – Plasma dextromethorphan concentrations may be elevated, increasing pharmacologic and toxic effects.
Sibutramine – A "serotonin syndrome" may occur, which may be characterized by CNS irritability, motor weakness, shivering, myoclonus and altered consciousness.

Dosage and Administration

Adults and children over age 12:
2-4 teaspoonsful (10-20mL) every 12 hours, not to exceed 8 teaspoonsful in a 24-hour period

Children ages 6 to 12:
1-2 teaspoonful (5-10mL) every 12 hours, not to exceed 4 teaspoonsful in a 24-hour period

Children ages 2 to 6:
½-1 teaspoonful (2.5-5mL) every 12 hours, not to exceed 2 teaspoonsful in a 24-hour period

Children under 2 years of age:
As directed by a physician

Cost Comparison (at commonly used dosages)

Selected Product Comparison:

Product	Price per 5mL	AWP*/10 days^
Tanafed DMX • dexchlorpheniramine 2.5mg • pseudoephedrine 75mg • dextromethorphan 25mg	1.69	135.48
Rhinosyn DM • chlorpheniramine 2mg • phenylephrine 5mg • dextromethorphan 15mg	0.12	9.96
Biodec DM • carbinoxamine 4mg • pseudoephedrine 60mg • dextromethorphan 15mg	0.10	3.84

*Average Wholesale Price: Facts and Comparisons (Medi-Span), St Louis, MO; January 2003.
^Price is based on the maximum daily doses as indicated for each product.

Conclusion

Tanafed DMX™ Suspension is used for the relief of nasal congestion and pressure, itchy nose, throat and eyes, sneezing, runny nose, and cough. There are a variety of antihistamine/decongestant/cough suppressant combination products available on the market. Pricing of Tanafed DMX™ Suspension is not favorably priced when compared to other similar agents.

Recommendation(s)

It is recommended to continue Tanafed DMX™ Suspension as a PA drug.

References

1. Tanafed DMX™ Suspension package insert. Alpharetta, GA: First Horizon Pharmaceutical; 8/02.
2. Drug Facts and Comparison, nasal decongestants. Facts and Comparisons, 2003. Available from: http://efactsweb.com.
3. Drug Facts and Comparison, antihistamines. Facts and Comparisons, 2003. Available from: http://efactsweb.com.
4. Drug Facts and Comparison, dextromethorphan. Facts and Comparisons, 2003. Available from: http://efactsweb.com.

Prepared by: Mary S. Peery, Pharm.D.
Date: February 19, 2003

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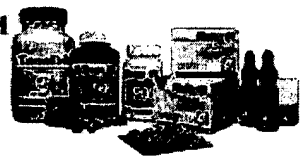

Viracin™ Selected condensed, plant tannins; Acerin as Zinc tannates

Viracin™, is an anti-bacterial/anti-viral tannate formula for the GI. It combines the most powerful phagicidal and virucidal herbal tannins available. It contains Norwegian Maple fruit, Babul bark and Wild rhubarb (*canaigre*). Viracin™ works in the same manner as Tanalbit®: attaching to the outer membrane of the target cell (in this case bacteria) which disables the cell and prevents proliferation and growth. Like Tanalbit® it is non-toxic with the occasional minimal side effect of constipation and/or diarrhea. If this occurs, reduction in dosage is suggested.

Viracin™ is designed for anti-bacterial use in the stomach and some areas of the GI tract *only* (it does not work systemically nor can it be used for venereal disease, herpes or diseases requiring intensive drug therapy) however it can help with the immune system in fighting against colds and flu.

Who should take Viracin™?

Viracin™ has applications for individuals with intestinal dysbiosis, including pathogenic overgrowth of *citrobacter freundii*. Viracin™ may help restore intestinal flora levels back to normal range by attacking pathogenic bacteria while in the stomach and large intestine. Viracin™ can be taken with Tanalbit®. Viracin™ can replace Tanalbit® therapies for stomach bacteria when casein allergies are known. (Tanalbit® contains casein)

Colds & Flu / Sinusitis

Viracin™ has applications for cold and flu prevent in addition to sinusitis. Suggested dosage is 6-8 capsules at the first sense of cold/flu and/or sinusitis.

*The statements contained herein have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Viracin™, Plant Tannin, 60 count

Contents: Zinc tannates 200 mg, Zinc (in tannates) 3 mg, L-Proline 15 mg

Inert/Additives ingredients: Magnesium Stearate

Suggested dosage: 2-3 capsules, 3 times daily. Best taken before meals or with a small protein meal. Do not take Viracin™ after meals or with other supplements/medications (allow at least 1 hour between supplements) as Viracin™ needs to work without competition from other supplements/medications. Optimal dosage is 9 capsules daily with a yeast/sugar free diet.

Dosage with Tanalbit: For bacteria/yeast, do not exceed more than 9 total of both; Suggested regimen is 4 capsules Viracin™ 5 capsules Tanalbit; Contact us for more information ≥

This formula is free of yeast, egg, gluten, corn, wheat, milk, starch, artificial colors or preservatives.

Viracin **$16.95** Order Now!

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≥ **Colds & Flu** Take 6-8 Viracin when cold/flu symptoms start; Viracin helps reduce illness time and may aid sinusitis

Interactions & Precautions: Tannins may interfere with the absorption/effectiveness of alkaline or steroidal medications. Avoid tannins when using Atropine, Cardec DM, Codeine, Ephedrine and Pseudoephedrine, Lomotil/Lonox, Loop Diuretics, Spironolactone, Theophylline/Aminophylli, Thiazide Diuretics, Triamterene. This is not an exhaustive list. | Viracin™ may cause constipation. If this occurs, use Magnesium/Vitamin C Supplement | Please consult with your physician prior to taking this tannin product |

Literature & Info How does Viracin work? ≥ Viracin (PDF file) ≥ Viracin Technical information ≥ Please contact us for literature/ samples≥	 Tanalbit®: Original anti-fungal formula; can be used alone or in conjunction with other tannin products for GI health	 Magnesium Ascorbate superior Magnesium & Vitamin C supplement for everyday therapy
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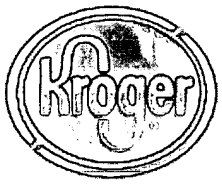

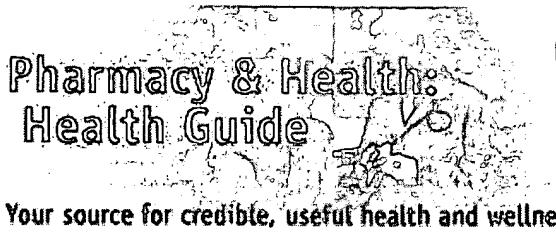

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Codeine

Combination drugs: Empirin® with Codeine, Fiorinal®, Phenergan® VC with Codeine, Phenergan® with Codeine, Robitussin® AC, Soma® Compound with Codeine, Tylenol® with Codeine

Codeine is a narcotic analgesic (pain reliever) derived from opium. It is used alone and in combination products to treat mild to moderate pain and as a cough suppressant.

Summary of Interactions with Vitamins, Herbs, and Foods

(for details about the summarized interactions, read the full article)

Avoid: *Reduced drug absorption/bioavailability*—Avoid these supplements when taking this medication since the supplement may decrease the absorption and/or activity of the medication in the body.	Tannin-containing herbs* such as green tea, black tea, uva ursi, black walnut, red raspberry, oak, and witch hazel
Depletion or interference	None known
Side effect reduction/prevention	None known
Supportive interaction	None known
Adverse interaction	None known

An asterisk (*) next to an item in the summary indicates that the interaction is supported only by weak, fragmentary, and/or contradictory scientific evidence.

Interactions with Herbs

Tannin-containing herbs

Tannins are a group of unrelated chemicals that give plants an astringent taste. Herbs with large amounts of tannins may interfere with the absorption of codeine and should not be taken together with codeine or codeine-containing products.[1] Herbs containing high levels of tannins include green tea (*Camellia sinensis*), black tea, uva ursi (*Arctostaphylos uva-ursi*), black walnut (*Juglans nigra*), red raspberry (*Rubus idaeus*), oak (*Quercus* spp.), and witch hazel (*Hamamelis virginiana*).

Interactions with Foods and Other Compounds

Food

Codeine commonly causes gastrointestinal (GI) upset. Codeine and codeine-containing products may be

taken with food to reduce or prevent GI upset.[2] A common side effect of narcotic analgesics, including codeine, is constipation. Increasing dietary fiber (fruits, vegetables, beans, whole-grain foods, and others) and water intake can ease constipation.

Alcohol

Alcohol causes a loss of coordination, impaired judgment, decreased alertness, drowsiness, and other actions. Narcotic analgesics, including codeine, cause similar loss of control. Combining codeine and alcohol increases the risk of accidental injury. People taking codeine-containing products should avoid alcohol.

References

1. Brinker F. Interactions of pharmaceutical and botanical medicines. *J Naturopathic Med* 1997;7(2):14–20.
2. Threlkeld DS, ed. Central Nervous System Drugs, Narcotic Agonist Analgesics. In *Facts and Comparisons Drug Information*. St. Louis, MO: Facts and Comparisons, Feb 1990, 243d.

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